

Exhibit 129

REVIEW ARTICLE

Dan L. Longo, M.D., *Editor*

Mucinous Ovarian Carcinoma

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NEARLY 239,000 NEW CASES OF OVARIAN CANCER (AND 152,000 ASSOCIATED deaths) are reported worldwide annually, with the highest incidence rates in North America and central and eastern Europe.^{1,2} The most common histologic subtype is high-grade serous ovarian cancer (accounting for 65% of cases). Other histologic subtypes include low-grade serous, endometrioid, clear-cell, and mucinous ovarian cancers, as well as ovarian carcinosarcoma.³⁻⁵ Mucinous ovarian cancer is a rare tumor, probably accounting for 3% of all epithelial ovarian cancers,^{6,7} and often presents a diagnostic and therapeutic conundrum for oncologists. For decades, the management of mucinous ovarian cancer was based on guidelines developed for serous ovarian cancer. However, experience with mucinous ovarian cancer and an understanding of its biologic features have shown that it is a unique disease requiring unique management. This review highlights the distinguishing features of mucinous ovarian cancer and provides an update on its molecular landscape and surgical and medical management.

A SEPARATE DISEASE ENTITY

The gene-expression profile of mucinous ovarian cancer is distinct from that of serous ovarian cancer.⁷ Sixty-five to 80% of mucinous ovarian cancers are diagnosed at an early stage, according to the classification of the International Federation of Gynecology and Obstetrics (FIGO stage I, defined as a tumor confined to a single ovary) (Table S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org).⁸ Patients with serous ovarian cancer tend to present at an advanced stage, with intraperitoneal spread in more than 80% of cases (Table 1).^{9,10} A potential explanation for this difference is that mucinous ovarian cancers are usually very large primary tumors (typically >15 cm in diameter) that generate symptoms while the disease is still localized to the ovary. Thus, the overall prognosis is much better for women with mucinous ovarian cancer than for those with other subtypes of epithelial ovarian cancer.⁸ Five-year overall survival among patients with localized mucinous ovarian cancer exceeds 90%; by contrast, when mucinous ovarian cancer has spread to the peritoneum in the abdominal cavity or beyond (stage III or IV), the estimated median overall survival is between 12 and 33 months.^{9,11-16}

Mucinous tumors are characteristically diagnosed in patients who are younger than patients in whom other epithelial ovarian cancers are diagnosed.^{6,9} In a recent analysis of data from the Surveillance, Epidemiology, and End Results (SEER) cancer registry, 26% of mucinous ovarian cancers were diagnosed in women younger than 44 years.⁹ Mucinous ovarian cancer is the most common histologic subtype in the subgroup of patients who are eligible for fertility-sparing surgery.^{17,18}

Table 1. Epidemiologic, Clinical, and Pathological Features of Mucinous Ovarian Carcinoma as Compared with High-Grade Serous Ovarian Cancer.*

Variable	Mucinous Ovarian Carcinoma (prevalence, 3%)	High-Grade Serous Ovarian Carcinoma (prevalence, 65%)
Age		
Median age at diagnosis (yr)	53	61
<44 yr at presentation (%)	26	7
Early stage at diagnosis (%)	65–80	5
Tumor marker	CEA or CA 19-9	CA-125
Risk factors	Smoking	Nulliparity, early menarche, late menopause, germline <i>BRCA1</i> or <i>BRCA2</i> mutations
Rate of response to platinum-based chemotherapy (%)	20–60	>70
Overall survival		
Stage 1, at 5 yr (%)	92	84
Advanced stage, median (mo)	12–33	35–60

* Some of the data presented in the table are from Ferlay et al.,¹ Reid et al.,² Peres et al.,⁹ and Torre et al.¹⁰ CEA denotes carcinoembryonic antigen.

In a series of 545 patients undergoing such surgery, 51% (280 patients) had mucinous ovarian cancer.¹⁷

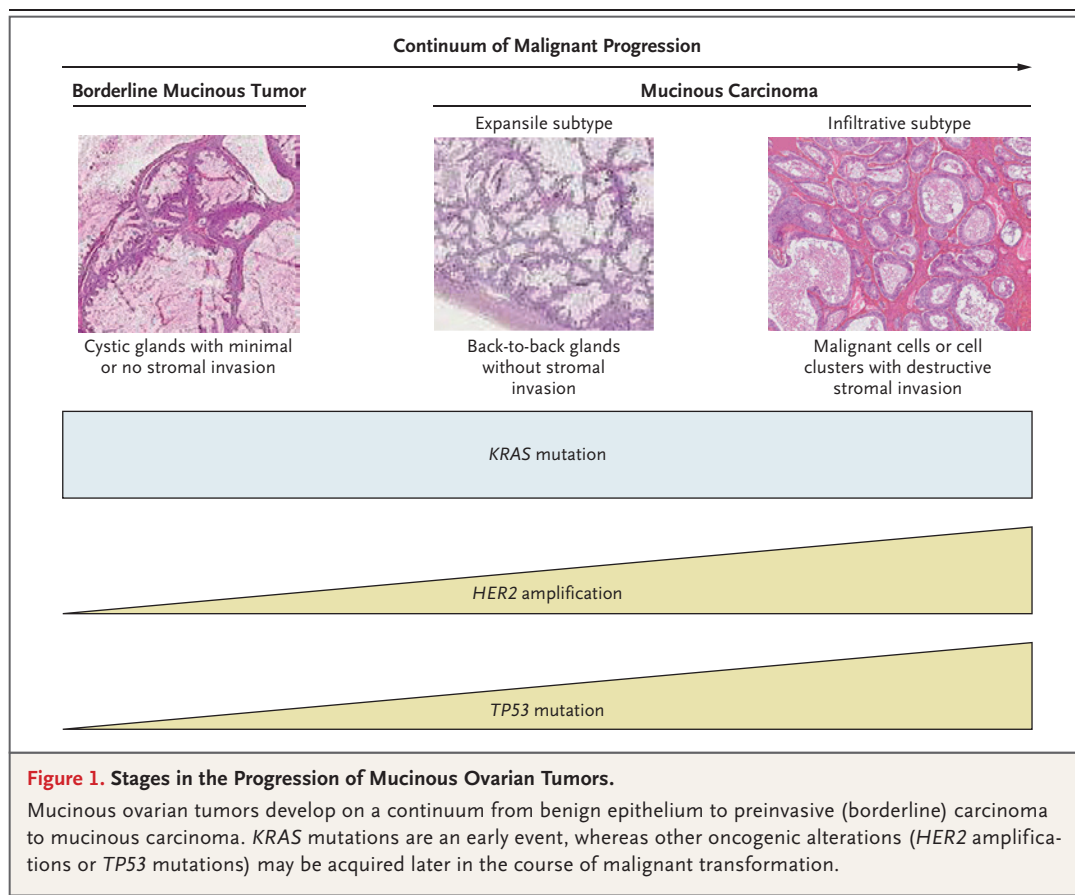
Most serous ovarian cancers originate in the fimbria of the fallopian tubes.¹⁹ Mucinous ovarian cancers appear to evolve in stepwise fashion from benign epithelium to a preinvasive lesion to carcinoma (Fig. 1).^{3,5,20,21} Mucinous ovarian cancer is frequently mixed with areas of mucinous cystadenoma or precancerous lesions (borderline mucinous tumor, borderline tumor with intraepithelial carcinoma, microinvasive carcinoma, or a combination of such lesions). This continuum of malignant progression is in stark contrast to the development of serous ovarian cancer and is similar to the development of colorectal cancer. *KRAS* mutations are observed in 40 to 65% of mucinous carcinomas. The same *KRAS* mutation has been detected in the carcinoma foci and in surrounding borderline malignant and benign areas, suggesting that the mutation is an early founder event.^{22–24} Other genomic alterations such as *HER2* amplification or *TP53* mutation are almost exclusively observed in the carcinomatous component of mucinous tumors, supporting the view that these alterations represent later events in malignant transformation.^{23,24} Another hypothesis regarding the histogenesis of mucinous ovarian cancers is that they may be

derived from transitional cells (Walthard cell nests are observed in 59% of mucinous neoplasms) or metaplasia at the fallopian tube–peritoneal junction.²⁵

Risk factors for serous ovarian cancer include nulliparity, early menarche, late menopause, and germline *BRCA1* or *BRCA2* mutations, none of which are risk factors for mucinous ovarian cancer. The only clinical risk factor associated with mucinous ovarian cancer is tobacco smoking. A genomewide association study of 1644 mucinous ovarian cancers identified susceptibility alleles at 2q13, 2q31.1, and 19q13.2 (the potential candidate gene is *HOXD9* for locus 2q31.1).²⁶ The incidence of mucinous ovarian cancer decreased by 5% annually in the United States between 1995 and 2009 and has been stable since 2009.¹⁰ These trends could be attributable to a decline in smoking or to improvements in the histologic diagnosis of mucinous ovarian cancer in the late 1990s and early 2000s.^{10,27,28}

DIAGNOSTIC CHALLENGE

Early reports probably overestimated the prevalence of mucinous ovarian cancer, with some studies reporting that they represented 10 to 15% of epithelial ovarian cancers.^{9,29,30} However, a central pathological review of ovarian tumors



initially classified as primary ovarian mucinous carcinomas revealed that 50 to 70% were in fact metastases from other sites. According to different reports, the true proportion of ovarian epithelial cancers that are mucinous ovarian cancers is closer to 1 to 3%.^{29,31}

RULING OUT OVARIAN METASTASES FROM NONOVARIAN OCCULT PRIMARY CANCER

A combination of clinical, pathological, and immunohistochemical investigations is useful in distinguishing a primary mucinous ovarian tumor from metastatic disease to the ovary (Krukenberg tumor) (Fig. 2).^{29,32,33} A comprehensive work-up is performed to rule out an occult gastrointestinal primary cancer (on the basis of colonoscopy and upper gastrointestinal endoscopy, including endoscopic ultrasonography) or a cervical, breast, or uterine cancer.^{29,32} These investigations are recommended if clinical or radiologic findings suggest a nonovarian primary cancer on the basis of tumor size (<10 cm

in diameter), the presence of bilateral tumors, peritoneal spread or another indication of advanced stage, or a combination of these findings (Fig. 2).²⁹

DIAGNOSING THE SUBTYPE OF MUCINOUS TUMOR

The diagnosis of mucinous ovarian carcinoma requires evidence of malignant proliferation covering an area of more than 10 mm² as determined on cross section. For decades, mucinous ovarian cancer was further classified as grade 1, 2, or 3 according to the presence or absence of nuclear atypia and the proportion of solid glandular component. However, in 2014, the World Health Organization (WHO) introduced a new diagnostic classification of mucinous ovarian carcinoma, with two categories according to the growth pattern: the expansile (confluent) subtype and the infiltrative subtype.⁵ The expansile subtype is characterized by a confluent glandular growth pattern, with little intervening normal ovarian stroma (minimal or no stromal in-

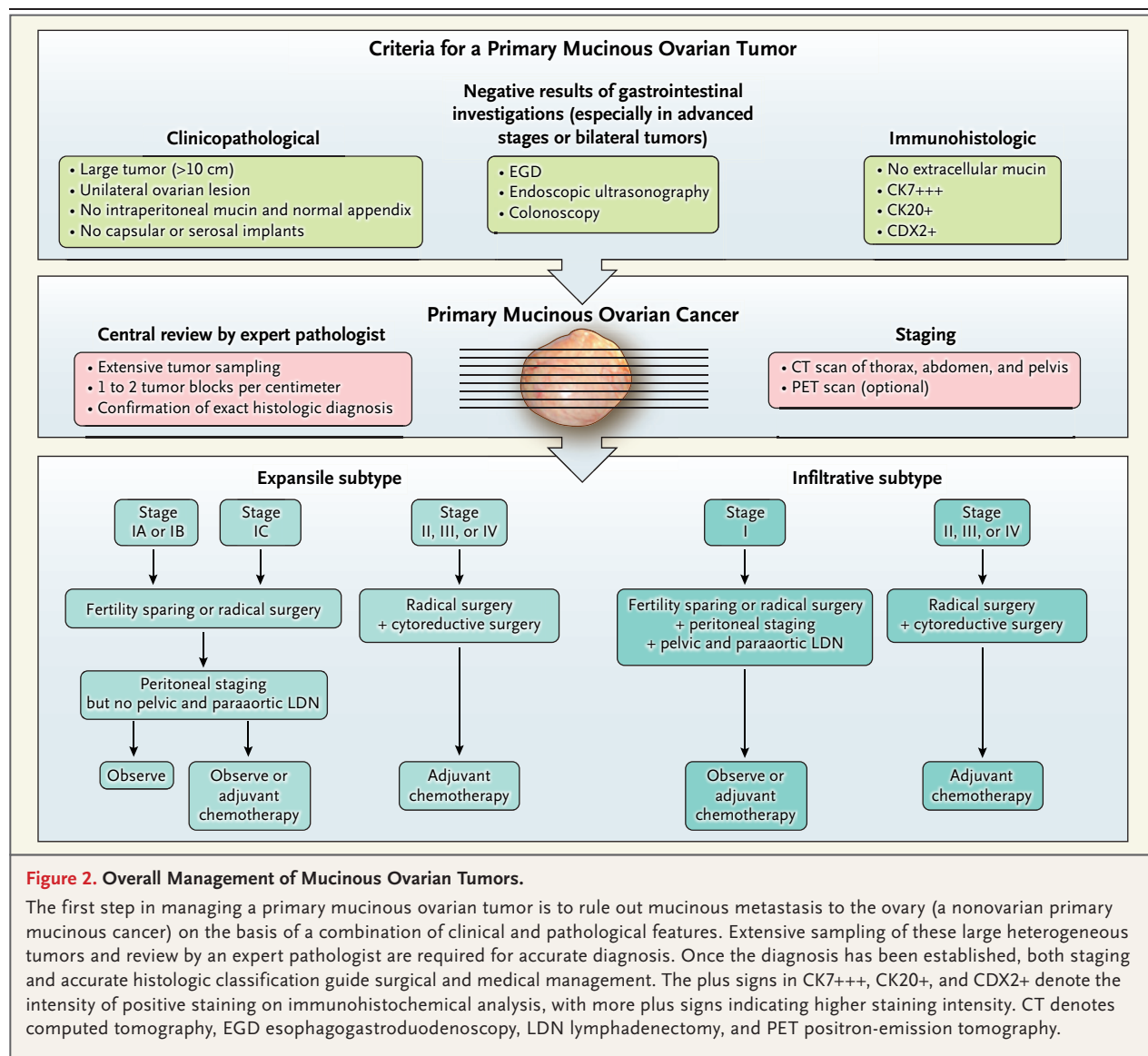


Figure 2. Overall Management of Mucinous Ovarian Tumors.

The first step in managing a primary mucinous ovarian tumor is to rule out mucinous metastasis to the ovary (a nonovarian primary mucinous cancer) on the basis of a combination of clinical and pathological features. Extensive sampling of these large heterogeneous tumors and review by an expert pathologist are required for accurate diagnosis. Once the diagnosis has been established, both staging and accurate histologic classification guide surgical and medical management. The plus signs in CK7+++, CK20+, and CDX2+ denote the intensity of positive staining on immunohistochemical analysis, with more plus signs indicating higher staining intensity. CT denotes computed tomography, EGD esophagogastroduodenoscopy, LDN lymphadenectomy, and PET positron-emission tomography.

vasion), whereas the infiltrative subtype is characterized by obvious evidence of destructive stromal invasion by malignant glands, cell nests, or individual cells and is often associated with a desmoplastic stromal reaction (Fig. 1).^{5,34}

PROGNOSTIC IMPLICATIONS OF THE WHO 2014 HISTOLOGIC CLASSIFICATION

The distinction between expansile and infiltrative subtypes is clinically important in stage I disease (Table 2), so surgical staging of these tumors is crucial.³⁻³⁸ The expansile growth pattern suggests a lower metastatic potential, and

several, albeit small, studies have confirmed that the risk of relapse for women with stage I expansile mucinous ovarian cancer is extremely low (3 recurrences were observed among 75 cases; 2 of the 3 were salvaged with secondary surgery).³⁴⁻³⁸ Moreover, more than 95% of women with expansile mucinous ovarian cancers present with stage I disease.^{34-38,40} Cases of the expansile subtype with peritoneal spread are very scarce (only 3 reported cases) (Table 2).^{35,37} In contrast, infiltrative mucinous ovarian cancer is more aggressive, with at least 26% of women presenting with more advanced, nonlocalized

Table 2. Clinical Characteristics and Outcomes of Mucinous Ovarian Cancer According to the Subtype.

Subtype and Study	Pathological Review	Total Enrollment	Stage IA	Stage IC	Higher Stage	Recurrences and Deaths
<i>number of patients</i>						
Expansile subtype						
Riopel et al., ³⁵ 1999	Yes	5		4*	1 at stage II	1 recurrence at stage II
Lee and Scully, ³⁴ 2000	Yes	12 (10 in follow-up)	12	0	0	0 recurrences
Rodríguez and Prat, ³⁶ 2002	Yes	15 (11 in follow-up)	10	5 (4 at stage IC1, 1 at stage IC2)	0	0 recurrences; 1 death from breast cancer
Muyldermans et al., ³⁷ 2013	Yes	23	11	10	2 at stage III	2 recurrences at stage III†
Gouy et al., ³⁸ 2018	Yes	29	13	16 (9 at stage IC1, 5 at stage IC2, 2 at stage IC3)	Not included	3 recurrences: 1 at stage IA, 1 at stage IC2, 1 at stage IC3; 1 death
Total		84	46	31	3	6 recurrences: 3 at stage I (3/81 [4%]), 3 at higher stage (3/3 [100%])
Infiltrative subtype						
Hoerl and Hart, ³⁹ 1998		19		15‡	4 at stage III	6 recurrences: 2 at stage I, 4 at higher stages; 5 deaths
Lee and Scully, ³⁴ 2000		13 (11 in follow-up)	6 (5 in follow-up)	0	3 at stage II, 3 at stage III, 1 at stage IV (5 in follow-up)	6 recurrences: 1 at stage IA, 5 at higher stages; 6 deaths
Rodríguez and Prat, ³⁶ 2002		19 (15 in follow-up)	8	3	1 at stage II, 6 at stage III, 1 at stage IV (6 in follow-up)	9 recurrences: 1 at stage IC1, 2 at stage IC2, 1 at stage II, 4 at stage III, 1 at stage IV; 7 deaths§
Muyldermans et al., ³⁷ 2013		21	9	3	9 at stage III	9 recurrences: 1 at stage IA, 1 at stage IC, 7 at stage III
Gouy et al., ³⁸ 2018		35	20	15 (7 at stage IC1, 7 at stage IC2, 1 at stage IC3)	Not included	6 recurrences: 2 at stage IA, 1 at stage IC1, 2 at stage IC2, 1 at stage IC3; 4 deaths¶
Total		107	43	21	28	36 recurrences: 14 at stage I (14/79 [18%]) and 22 at stage III or IV (22/24 [92%])

* In this study, four patients with the expansile subtype had stage I disease that was not classified as either stage IA or stage IC.

† One additional patient with stage I disease died from acute myeloid leukemia while free of the ovarian disease.

‡ In this study, 15 patients with the infiltrative subtype had stage I disease that was not classified as either stage IA or IC.

§ One additional patient with stage I disease died from thyroid cancer while free of the ovarian disease. In the same series, two patients with recurrent infiltrative disease (one at stage III and one at stage IV) survived with persistent disease.

¶ One patient with a recurrence survived but with persistent disease.

disease at diagnosis; in 17 to 30% of patients who appear to have stage I disease, lymph-node metastases are detected (as compared with no women with expansile mucinous ovarian cancer).³⁴⁻³⁹ Even if the cancer is diagnosed at an early stage, the prognosis for women with infiltrative mucinous ovarian cancer is much poorer, with fatal relapses reported for 15 to 30% of patients with stage I disease (Table 2).³⁴⁻³⁸ Thus, the distinction between stage I expansile and stage I infiltrative subtypes is crucial, since it may influence indications for staging lymphadenectomy or adjuvant chemotherapy.

SURGICAL MANAGEMENT

MANAGEMENT OF EARLY-STAGE MUCINOUS CARCINOMA

For young patients wishing to preserve their fertility, a unilateral salpingo-oophorectomy is usually proposed, with peritoneal staging procedures (cytology, peritoneal biopsies, and omentectomy). In older patients, bilateral salpingo-oophorectomy is preferred. The priority is to choose the best surgical approach (laparotomy or a minimally invasive laparoscopic approach) for minimizing the risk of perioperative tumor rupture. Such a rupture would alter the FIGO stage and influence both surgical and medical management of histologically confirmed mucinous ovarian cancer. Unilateral salpingo-oophorectomy is a reasonable approach in women with stage I disease who wish to preserve their fertility. The risk of recurrence is lower than that reported for women with stage I serous cancers (6% vs. 20%, $P < 0.001$).^{17,40} Only one study has evaluated the results of fertility-sparing surgery in women with the expansile subtype of mucinous ovarian cancer and those with the infiltrative subtype, and the results suggest that it could be safely used for both subtypes.⁴¹

A small fraction of patients with macroscopically normal findings on surgical exploration have microscopic peritoneal spread (positive cytologic results in 5.7% of cases or microscopic involvement of the omentum or peritoneal-biopsy specimen in 1.7% of cases) or appendiceal spread (metastasis in 1.1% of cases), but peritoneal or appendiceal spread remains a rare event as compared with disease spread in other epithelial subtypes (Table S2 in the Supplementary Appendix).^{42,43}

The rate of nodal spread is very low in cases of apparent stage I mucinous ovarian cancer (<2%).^{44,45} However, the higher rate of nodal involvement in stage I infiltrative mucinous ovarian cancer (17 to 30%) suggests that pelvic and para-aortic lymphadenectomy should be proposed for all patients with infiltrative disease, regardless of stage, but can be safely omitted for patients with stage I expansile disease.^{37,42}

MANAGEMENT OF STAGE III OR IV MUCINOUS OVARIAN CANCER

The prognosis for women with stage III or IV mucinous ovarian cancer is poorer than the prognosis for women with other, more common subtypes (particularly serous or endometrioid ovarian cancer) and may be related to a poorer response to chemotherapy (Table S3 in the Supplementary Appendix).^{11,16,30,46-48} Some authors have argued that this poor prognosis is due to the inherently aggressive biology of the tumor and the questionable technical feasibility of complete resection, raising doubts regarding the usefulness of an aggressive debulking surgery in women with stage III or IV mucinous ovarian cancer.¹³ Conversely, in a series involving 50 patients with stage III or IV mucinous ovarian cancer, overall survival was increased by a factor of 3.8 among patients who underwent optimal debulking surgery.⁴⁷ Finally, in an analysis of three randomized trials involving 3126 patients (147 with mucinous ovarian cancer), the size of the residual disease was shown to significantly affect overall and event-free survival in a multivariate analysis of data for patients with mucinous ovarian cancer.⁴⁹ In conclusion, debulking surgery with the objective of a macroscopically complete resection remains a cornerstone of management for advanced mucinous ovarian cancer.

MEDICAL MANAGEMENT

The prognosis for women with mucinous ovarian cancer depends on the stage of disease.^{13,49} Overall survival is higher for the majority of patients presenting with stage I disease than for those with nonmucinous histologic subtypes (hazard ratio, 0.52; 95% confidence interval [CI], 0.30 to 0.92). However, the trend is the inverse for women with stage III or IV mucinous ovarian cancer, who have significantly lower overall sur-

vival than women with nonmucinous histologic subtypes (hazard ratio, 2.81; 95% CI, 2.47 to 3.21).⁵⁰ Retrospective series have confirmed lower response rates to first-line platinum-based chemotherapy (mainly carboplatin and paclitaxel) among women with mucinous ovarian cancer (13 to 60%) than among women with serous ovarian cancer (64 to 87%) (Table S3 in the Supplementary Appendix).^{11,16,30,46-48,50}

Given the histologic similarities between primary mucinous ovarian cancer and gastrointestinal carcinomas and the *in vitro* synergy between oxaliplatin and fluorouracil in preclinical models of mucinous ovarian cancer, empirical use of chemotherapeutic regimens that are traditionally used for gastrointestinal cancers has been tested.^{51,52} Gynecologic Oncology Group trial 0241 (involving European, Australian, Korean, and North American groups) was designed to study the activity of a colorectal cancer regimen in women with newly diagnosed metastatic mucinous ovarian cancer. A phase 3 trial randomly assigned women to receive treatment with either paclitaxel and carboplatin (control group) or the combination of capecitabine and oxaliplatin.³¹ In addition, there was a secondary randomization in which women were assigned to receive bevacizumab or placebo in order to test the activity of antiangiogenesis therapy. The trial had slow accrual and was closed prematurely. Preliminary results based on the small group of patients (50) who underwent randomization showed no significant difference in progression-free survival among the treatment groups and confirmed a low objective response rate (10 of the 50 women, or 20%, had a response), regardless of the treatment regimen.³¹

Neoadjuvant treatment for advanced ovarian cancer has been tested in the European Organization for Research and Treatment of Cancer (EORTC) 55971 and CHORUS trials. The studies compared initial surgery with a strategy of neoadjuvant chemotherapy.^{53,54} Patients with mucinous cancers accounted for only 1 to 3% of the patients, making it impossible to draw any conclusions.

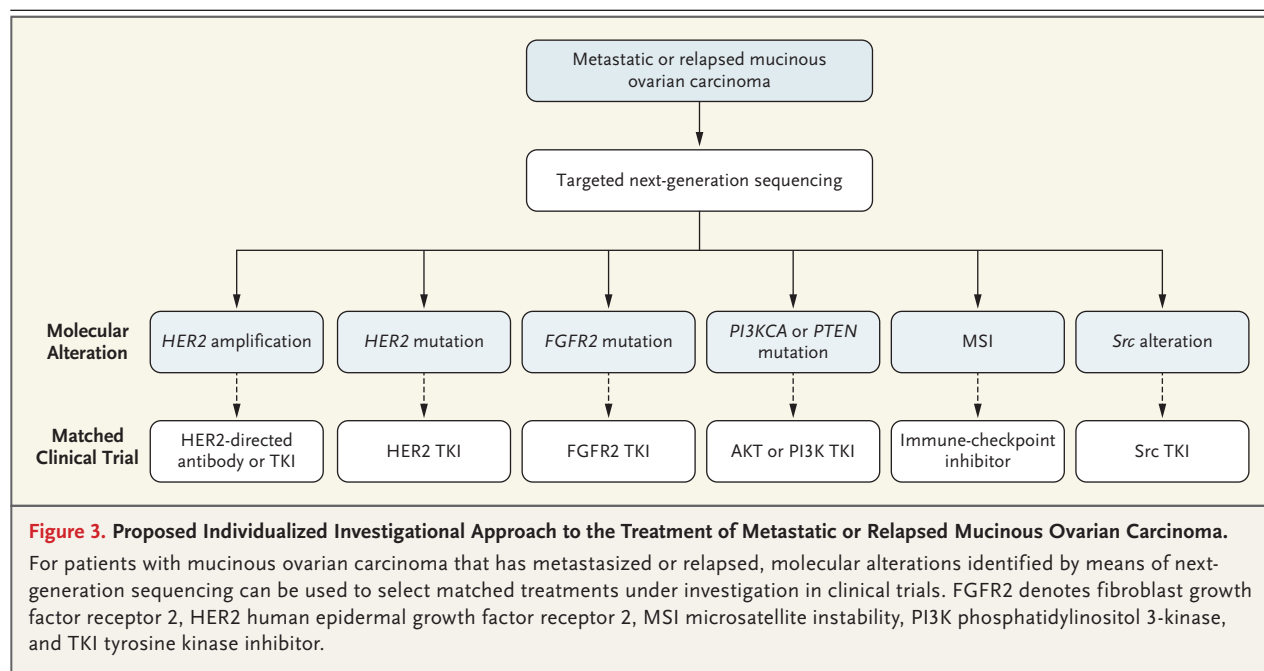
There is a dearth of data from randomized clinical trials evaluating adjuvant chemotherapy in early-stage mucinous ovarian cancer. Various national and international guidelines provide statements about indications for adjuvant chemo-

therapy to help guide physicians, but these statements are not based on clear evidence of a benefit. The National Comprehensive Cancer Network (NCCN) guidelines recommend surgery alone for stage IA or IB mucinous ovarian cancer and adjuvant platinum-based chemotherapy (carboplatin and paclitaxel, or oxaliplatin with fluorouracil or capecitabine) for stage II or more advanced disease. In the case of stage IC mucinous ovarian cancer, the NCCN guidelines recommend either observation or adjuvant chemotherapy (www.nccn.org/patients/guidelines/ovarian/index.html#69/z).

Given the previously mentioned retrospective studies supporting the prognostic information provided by the growth pattern, other European guidelines have further refined treatment recommendations for stage I mucinous ovarian cancer according to the expansile versus infiltrative subtype (Fig. 2). For stage IA or IB expansile mucinous ovarian cancer, which is considered to be low risk, observation alone is recommended, whereas adjuvant chemotherapy is discussed for stage IC expansile mucinous ovarian cancer and is proposed for most cases of stage I infiltrative mucinous ovarian cancer, thus further underscoring the essential role of high-quality pathological review in the management of these rare tumors (www.ovaire-rare.org/TMRG/medecin/adenocarcinome_mucineux.aspx) (Fig. 2C).⁵⁵

MOLECULAR LANDSCAPE OF MUCINOUS OVARIAN CANCER AND THERAPEUTIC OPPORTUNITIES

Serous ovarian cancers lack genomic alterations in typically actionable driver oncogenes such as *HER2*, *EGFR*, *ALK*, and *BRAF* but are characterized by defects in homologous recombination DNA-repair genes, such as *BRCA1* or *BRCA2*. This deficiency in homologous recombination has been successfully exploited with the use of poly(adenosine diphosphate-ribose) polymerase (PARP) inhibitors. This drug class represents the first targeted therapy with a demonstrated clinical benefit for women who have relapsed high-grade ovarian cancer. Mucinous ovarian cancers are not associated with *BRCA* mutations or defects in homologous recombination, making them unlikely to benefit from PARP inhibitors. However, they frequently display mutations or amplifications that might be targetable. The most frequent alterations are *KRAS* mutations (in 40 to



65% of cases), *c-MYC* amplifications (in 65%), *HER2* amplifications (in 20 to 38%), and *TP53* mutations (in 50 to 75%). In addition, other alterations have been identified at lower frequencies, such as homozygous deletions in *CDKN2A/B* (in 25% of cases), mutations in *PI3KCA* (in 13%), and mutations in *PTEN*, *BRAF*, *FGFR*, *KIT*, or *STK11* (in 2 to 5%).^{23,24,56-60}

These genomic profiling studies allow mucinous ovarian cancers to be grouped into therapeutically relevant subsets (Fig. 3). For example, *KRAS* mutations and *HER2* amplifications tend to be mutually exclusive.^{23,60} The subset of *HER2* (human epidermal growth factor receptor 2)-positive tumors with wild-type *KRAS* may be particularly suited to *HER2*-directed therapies such as trastuzumab. Anecdotal objective responses have been described in case reports of patients with metastatic, *HER2*-amplified, mucinous ovarian cancer treated with either trastuzumab alone or trastuzumab combined with the oral tyrosine kinase inhibitor lapatinib.^{61,62} The identification of *HER2* or *HER3* mutations in an additional 2 to 12% of patients could justify the inclusion of such patients in basket trials of *HER* inhibitors.^{23,58}

EGFR amplification or mutations in *BRAF*, *FGFR*, or *STK11* have been detected in *HER2*-negative tumors with wild-type *KRAS*, suggesting that

these tumors may be responsive to inhibitors of *EGFR* (epidermal growth factor receptor), *BRAF*, *FGFR2* (fibroblast growth factor receptor), or *mTOR* (mammalian target of rapamycin), respectively. The absence of a *KRAS* mutation identifies a subset of patients with colorectal cancer who are more likely to benefit from the *EGFR*-inhibiting antibody, cetuximab. Preclinical studies have shown that cetuximab inhibits proliferation in mucinous ovarian cancer cell lines with wild-type *KRAS* and in a single in vivo model, whereas it has no antitumor effect in a model of *KRAS*-mutated mucinous ovarian cancer.⁶³

Most mutations in the *PI3K* (phosphatidylinositol 3-kinase) pathway occur with a *KRAS* mutation, and preclinical studies have shown synergy between *MEK* (mitogen-activated protein kinase) and *PI3K* inhibition in mucinous ovarian cancer cell lines with *KRAS* mutations.⁶⁴ Although the number of patients was small, a phase 1 trial of molecularly guided therapies for rare subtypes of ovarian cancer showed encouraging objective responses to combined *MEK* and *PI3K* inhibition in patients with *KRAS*-mutated ovarian cancer.⁶⁵

TP53 mutations are detected at a remarkably high frequency in mucinous ovarian cancer (in 50 to 75% of cases).^{23,66} *APR-246* is a small molecule designed to restore wild-type p53 function, whereas the *WEE1* inhibitor, *AZD1775*, abrogates

the G2-M cell-cycle checkpoint, selectively sensitizing p53-deficient cells to DNA-damaging agents.⁶⁷ Both agents are being investigated in clinical trials of TP53-mutated tumors.

Finally, defects in the mismatch-repair pathway of DNA repair that result in a tumor with microsatellite instability have been detected in 15 to 20% of patients with mucinous ovarian cancer.⁶⁸⁻⁷⁰ Given that tumors with microsatellite instability have high mutation burdens and dense immune infiltrates that are characteristic of other tumor types that respond to immune-checkpoint inhibition, enthusiasm is high for testing inhibitors of PD-1 (programmed death 1) or PD-L1 (programmed death ligand 1) in the subset of mucinous ovarian cancers with microsatellite instability.⁷¹

FUTURE DIRECTIONS

Important questions remain regarding the management of high-risk, localized mucinous ovarian cancer (stage I infiltrative subtype or stage IC expansile subtype). What are the criteria for selecting patients with high-risk stage I disease for adjuvant treatment? What is an ideal cytotoxic regimen? Will therapy that has some activity against gastrointestinal tumors have meaningful activity against mucinous ovarian cancer? In the future, targeted therapy may be worth testing in patients who have mucinous ovarian cancer with selected genetic alterations such as *HER2* muta-

tions or microsatellite instability (Fig. 3).^{72,73} The rarity of the tumor mandates international collaboration to evaluate new therapies in a timely fashion.

In line with these questions, the Fifth Ovarian Cancer Consensus Conference of the Gynecologic Cancer InterGroup identified four key areas for further research in mucinous ovarian cancer: improvement in the histologic criteria for diagnosis, definition of the optimal surgical and medical approaches to the management of high-risk localized disease, identification of an active cytotoxic regimen, and enrollment of patients in clinical trials of new therapeutics.⁷⁴

Dr. Morice reports receiving advisory board fees from Roche, lecture fees from Johnson & Johnson, and fees for participating on a board from Clovis; Dr. Gouy, receiving consulting fees from Roche; and Dr. Leary, receiving fees for serving as chief investigator or principal investigator on clinical trials, travel support paid to her institution, and advisory board fees from AstraZeneca; fees for serving as principal investigator on clinical trials, travel support paid to her institution, and advisory board fees from Clovis; travel support and advisory board fees from Tesaro; advisory board fees from Gridstone, Seattle Genetics, and Biocad; grant support paid to her institution from Merus and Inivata; fees for serving as chief investigator or principal investigator on a clinical trial paid to her institution from Roche, Pfizer, MSD, BMS, and Pharmamar; and grant support paid to her institution, fees for serving as chief investigator on a clinical trial, and advisory board fees from GamaMabs. No other potential conflict of interest relevant to this article was reported.

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Exhibit 130

UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

DEANE BERG,)	CIV. 09-4179-KES
)	
Plaintiff,)	
)	
vs.)	MEMORANDUM OPINION
)	AND ORDER
JOHNSON & JOHNSON;)	
JOHNSON & JOHNSON)	
CONSUMER COMPANIES, INC.;)	
LUZENAC AMERICA, INC.;)	
JOHN DOES/JANE DOES 1-30;)	
UNKNOWN BUSINESSES)	
AND/OR CORPORATIONS A-Z,)	
)	
Defendants.)	

Defendants Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. move for summary judgment on all of plaintiff's claims (Docket 149) and also move to exclude the testimony of four of plaintiff's experts (Dockets 140, 143, 145, and 147). Defendant Luzenac America, Inc. joins in the motions (Dockets 151, 153, 155, 156, and 157). For the following reasons, defendants' motions to exclude are granted in part and denied in part. Defendants' motion for summary judgment is denied.

FACTUAL BACKGROUND

Berg was diagnosed with ovarian cancer in December of 2006. She was 49 years old at the time. Prior to her diagnosis, Berg used Johnson & Johnson products—Johnson's Baby Powder and Shower to Shower—to dust her

perineum for feminine hygiene purposes. She applied the products on a daily basis from 1975 until 2007.

Talc is one of the main ingredients in Johnson's Baby Powder and Shower to Shower. Talc is a naturally occurring mineral that is mined from the ground and used in various applications. Luzenac supplies talc to Johnson & Johnson.

Research has been ongoing studying how talc affects the female reproductive system for a number of years. For example, Dr. Daniel Cramer, one of Berg's proposed experts, published a study in 1982 that found that an association existed between the application of talc to a woman's genital area and the development of ovarian cancer. Defendants stayed current on the various studies that analyzed any potential hazards associated with talc.

Berg alleges that her application of talc to her perineum caused her ovarian cancer and brought this product liability action against defendants because their products did not include any warnings regarding the possible hazards of applying talc to a woman's perineum. Berg has identified four expert opinions in support of her claims.

First, Dr. Cramer is an epidemiologist and is prepared to testify that talc use in the genital area has a strong causal association with ovarian cancer. Further, Dr. Cramer's opinion is that Berg's frequent application of talc to her genital area was "the major cause of her invasive serous ovarian cancer[.]"
Docket 148-1 at 18.

Second, Dr. Gary Rosenthal is a toxicologist and is prepared to testify about talc's immunotoxic potential and how such potential relates to ovarian cancer. His opinion is that Berg's frequent talc use "played a role in disease processes leading to her ovarian cancer." Docket 144-1 at 11.

Third, Dr. John Godleski is an expert in microscopy, and he examined tissues taken from Berg's reproductive system following her diagnosis of ovarian cancer. He is prepared to testify that talc particles were present in Berg's tissues.

Fourth, Dr. David R. Lenorovitz and Dr. Edward E. Karnes are experts in the field of forensic human factors and warnings. Their designation as experts is to: (1) ascertain if talc posed a hazard to the populace; (2) ascertain if any such hazard was open and obvious to a reasonable user; (3) determine if there was a feasible way to place a warning on the talc product; and (4) determine if there was a financially and technically reasonable alternative to talc. Docket 173 at 2.

MOTIONS TO EXCLUDE EXPERT TESTIMONY

In this diversity action, federal law governs whether expert testimony is admissible. *Wagner v. Hesston Corp.*, 450 F.3d 756, 760 (8th Cir. 2006). Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. *Russell v. Whirlpool Corp.*, 702 F.3d 450, 456 (8th Cir. 2012). The rule provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill,

experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. In applying Rule 702, the trial judge becomes a “gatekeeper” who screens evidence to ensure its reliability and relevance. *Russell*, 702 F.3d at 456. “The rule clearly is one of admissibility rather than exclusion.”

Sappington v. Skyjack, Inc., 512 F.3d 440, 448 (8th Cir. 2008). An expert’s opinion should be excluded “only if it is so fundamentally unsupported that it can offer no assistance to the jury.” *Id.*

The district court applies a three-part test when screening proposed testimony for experts under Rule 702:

First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001). To satisfy the reliability requirement, the party offering the expert testimony must show by a preponderance of the evidence “that the methodology underlying [the expert’s] conclusions is scientifically valid.” *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010). In making the reliability determination, the court may consider: (1) whether the theory or technique can be or has been tested; (2) whether the

theory or technique has been subjected to peer review or publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operations; and (4) whether the theory or technique is generally accepted in the scientific community. *Russell*, 702 F.3d at 456. Additional factors to consider include: "whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Polski v. Quigley Corp.*, 538 F.3d 836, 839 (8th Cir. 2008). "This evidentiary inquiry is meant to be flexible and fact specific, and a court should use, adapt, or reject" these factors as the particular case demands. *Russell*, 702 F.3d at 456.

When making this inquiry, the court should focus on "principles and methodology, not on the conclusions that they generate." *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993)). At times, conclusions and methodology are not entirely distinct from one another, and the court "need not completely pretermitt judicial consideration of an expert's conclusions." *Id.* With these principles in mind, the court will now address defendants' motions to exclude expert testimony.

I. Dr. Daniel Cramer

Defendants' sole argument in support of their motion to exclude Dr. Cramer's testimony goes to the issue of whether his testimony is reliable.¹ Defendants attack Dr. Cramer's testimony regarding both specific causation and general causation, arguing that the testimony put forth to support each is not reliable. For purposes of defendants' motion to exclude Dr. Cramer's testimony, the court only considers whether the testimony is admissible and does not consider whether it is sufficient to prove an element in plaintiff's case.² See *Daubert*, 509 U.S. at 596 (noting the difference between admissibility and sufficiency).

Dr. Cramer is the Professor of Obstetrics, Gynecology, and Reproductive Biology at Harvard Medical School and is a practicing obstetrician and gynecologist. He has a doctorate degree in epidemiology from the Harvard School of Public Health.

Dr. Cramer's expert report relies on epidemiology³ to address two issues:
(1) "the association between use of cosmetic talc powders in the genital area and

¹ It appears to be undisputed that Dr. Cramer is qualified to give expert testimony and that his testimony is relevant.

² Sufficiency is addressed in the portion of this order dealing with defendants' motion for summary judgment.

³ Epidemiology is the "field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations." Reference Manual on Scientific Evidence 551 (3d ed. 2011), *available at* 2011 WL 7724261, *2.

ovarian cancer with regard to the likelihood that this is cause-and-effect” and (2) “the possible relevance of talc use to the occurrence of ovarian cancer in the specific case of Ms. Deane Berg[.]” Docket 148-1 at 3. The report concludes by opining that (1) there is a causal association between the use of talc and ovarian cancer, and (2) chronic talc use was the major cause of Berg’s invasive serous ovarian cancer. *Id.* at 18.

Defendants make two arguments in support of their motion to exclude Dr. Cramer’s testimony.⁴ First, they argue that Dr. Cramer’s report is inadmissible because it fails to rule out alternative causes of Berg’s cancer. Second, they argue that Dr. Cramer’s report is inadmissible because the odds ratios established in the report and Dr. Cramer’s interpretations of those odds ratios stem from unreliable methods.

A. Ruling Out Alternative Causes

Defendants argue that Dr. Cramer’s methodology is not reliable because he fails to rule out alternative causes of Berg’s cancer. Defendants rely on these four Eighth Circuit Court of Appeals opinions to support their proposition that Dr. Cramer was required to rule out alternative causes of Berg’s cancer:

Barrett, 606 F.3d 975; *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893 (8th

⁴ Defendants argue extensively in their briefs that Dr. Cramer’s testimony fails to establish either specific or general causation. Such arguments go to the sufficiency of Dr. Cramer’s testimony and not the admissibility of it. Because a motion to exclude expert testimony is concerned only with admissibility, these arguments will not be addressed in this part of the order.

Cir. 2008); *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748 (8th Cir. 2006); and *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202 (8th Cir. 2000). None of these cases, however, require an epidemiologist to rule out all alternative causes in order for his testimony to be admissible.

In *Barrett*, the Eighth Circuit found that the district court did not abuse its discretion when it limited the expert testimony of a toxicologist and a treating physician. 606 F.3d at 981-82. The toxicologist conceded that she lacked “significant scientific knowledge underpinning [her] opinion and that she did not rule out alternative causes of [plaintiff’s] injury. . . . Her opinion . . . was admittedly based on assumption, without any scientific testing or exposure analysis.” *Id.* at 981. The treating physician was not allowed to testify about the cause of the plaintiff’s toxic exposure because he “assumed that [plaintiff] had been injured by hydrogen sulfide gas exposure without any scientific verification and without considering any alternative causes.” *Id.* at 982. Neither expert witness was offering epidemiologic evidence. Both experts had glaring deficiencies in their opinions because they failed to do any scientific verifications, relied on unsupported assumptions, and did not consider alternative causes.

In *Bland*, the Eighth Circuit found that the district court did not abuse its discretion by excluding a treating physician’s expert testimony. 538 F.3d at 897-98. The treating physician intended to testify about the differential

diagnoses that he conducted. *Id.* at 897. “A differential diagnosis is a technique that identifies the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated.” *Bland*, 538 F.3d at 897. The treating physician’s differential diagnosis was inadmissible because he failed to eliminate other possible causes. *Id.* The very nature of a differential diagnosis requires a consideration and elimination of other possible causes. By failing to consider other causes, a differential diagnosis cannot, by definition, be reliable. Thus, *Bland* stands for the proposition that an admissible differential diagnosis requires the expert to consider and eliminate other possible causes. *Bland* does not stand for the proposition that an expert offering epidemiologic evidence must rule out all other possible causes for his testimony to be admissible.

In *Marmo*, the Eighth Circuit found that the district court acted within the bounds of discretion when it precluded a toxicologist from testifying. 457 F.3d at 758. The toxicologist did not examine the plaintiff, did not inquire about other toxic exposures, did not exclude confounding factors, and “admitted that the causation standard she employed was not subject to expression in terms of a potential rate of error and was a much lower standard than medical causation.” *Id.* *Marmo* does not support defendants’ proposition that an expert offering epidemiologic evidence must rule out all other possible causes for his testimony to be admissible.

Lastly, in *Turner* the Eighth Circuit concluded that the district court did not abuse its discretion by excluding a treating physician's expert opinion. 229 F.3d at 1208-09. Just as in *Bland*, the treating physician's opinion was based on a differential diagnosis in which he "admitted that he made no attempt to consider all the possible causes, or to exclude each potential cause until only one remained, or to consider which of two or more non-excludable causes was the more likely to have caused the condition." *Id.* at 1208. Again, failing to properly administer a differential diagnosis resulted in an inadmissible differential diagnosis. But *Turner* does not require that an epidemiologist perform a differential diagnosis, which would require consideration of other possible causes.

After a review of these cases, the appropriate legal proposition created from these opinions is that an expert witness who performs a differential diagnosis must consider all other possible causes and exclude each potential cause until only one remains, or consider which of two or more non-excluded potential causes was the more likely to have caused the condition. Dr. Cramer, however, does not claim to have performed a differential diagnosis. Indeed, his testimony is based on epidemiology. Moreover, Dr. Cramer's report indicates that he did in fact consider other possible causes of Berg's cancer. Therefore, Dr. Cramer's opinion will not be excluded on the basis that he failed to rule out all alternative causes. See *In re Prempro Prod. Liab. Litig.*, 586 F.3d 547, 566 (8th

Cir. 2009) (noting that an expert’s “explanations as to conclusions not ruled out went to weight and not admissibility”).

B. Dr. Cramer’s Methodology

Defendants’ second argument goes to the general methodology applied by Dr. Cramer. In his expert report, Dr. Cramer notes that, in general, there is an odds ratio⁵ of 1.33 between perineal talc use and ovarian cancer. Dr. Cramer further asserts that a woman with Berg’s characteristics has an odds ratio of 3.53. Defendants argue that the 3.53 odds ratio established in Dr. Cramer’s report comes from unreliable methods. The court begins its analysis by addressing defendants’ specific concerns with Dr. Cramer’s findings and then moves to a more general examination of the methodology employed by Dr. Cramer.

First, defendants claim Dr. Cramer’s testimony is unreliable because it conflicts with existing scientific literature that shows the appropriate odds ratio is more in line with the 1.33 figure that Dr. Cramer generated. But there is “no requirement that published epidemiological studies supporting an expert’s opinion exist in order for the opinion to be admissible.” *Bonner v. ISP Tech., Inc.*,

⁵ An odds ratio “expresses in quantitative terms the association between exposure to an agent and a disease.” Reference Manual on Scientific Evidence 568 (3d ed. 2011), *available at* 2011 WL 7724261, *10-*11. Typically, if the odds ratio equals 1.0, the risk in exposed individuals is the same as the risk in unexposed individuals. *Id.* at 567. The greater the odds ratio the greater the risk in exposed individuals. *Id.* For example, an odds ratio of 4.0 indicates that the risk of disease in the exposed group is four times as high as the risk of disease in the unexposed group. *Id.*

259 F.3d 924, 929 (8th Cir. 2001). Dr. Cramer’s testimony will be admitted so long as his methodology is reliable even if his conclusions are novel. *See id.* (“The district court could not exclude scientific testimony simply because the conclusion was ‘novel’ if the methodology and the application of the methodology were reliable.”).

Second, defendants argue that the testimony is unreliable because he “cherry-picked” data in order to form an opinion solely for purposes of litigation. “That an expert testifies based on research he has conducted independent of litigation provides important, objective proof that the research comports with the dictates of good science.” *Lauzon*, 270 F.3d at 692. Dr. Cramer has been studying the association between talc use and ovarian cancer since at least 1982. He has published several articles on the subject over the past 30 years. While it is true that his specific findings relevant to this case were generated during the course of litigation, the methods he employed in reaching his conclusions are very similar to the methods used in his previous research. Indeed, the data he used to generate the odds ratios came mostly from his past research. The only difference between his past and present research seems to exist in how he categorized his data. Defendants label this “cherry-picking.” The court views it as simply looking at the existing data from a different perspective. Therefore, the court concludes that although Dr. Cramer’s opinion was

developed during the course of this litigation, the opinion “naturally flowed from [his] research.”⁶ *Polski*, 538 F.3d at 839.

Third, defendants assert that the testimony is unreliable because Dr. Cramer’s conclusions conflict with his non-litigation research and also conflict internally. If Dr. Cramer’s previous, or even present, research contradicts his testimony in this case, certainly defendants can challenge his credibility during cross-examination. *See Kuhn*, 686 F.3d at 627 (noting that when an expert offers testimony that conflicts with his opinion, the appropriate response from the court is to allow the opposing party to challenge the credibility of the expert). But unless his methodology is unreliable, the court will not preclude his testimony.

Defendants also identify alleged inconsistencies in Dr. Cramer’s findings (i.e., noting a protective effect for limited talc application). Again, this is a criticism of Dr. Cramer’s results, not his methodology. Defendants will have the chance at trial during cross examination to attack his results.

The court will now analyze Dr. Cramer’s methodology from a broader perspective under the seven factors articulated by the Eighth Circuit in *Polski*

⁶ Additionally, Dr. Cramer testified that he is attempting to get his latest findings published in a scientific journal. This is important because it shows that Dr. Cramer has a stake in his findings independent from this litigation. Suspensions would arise if an expert were to propose testimony for litigation and then refuse to stand behind those findings in the scientific community. That is not the case here.

and previously set forth herein, while also addressing additional issues raised by defendants.⁷

As indicated in his report, Dr. Cramer performed a case-control study⁸ to generate his final conclusions. A case-control study is commonplace in the field of epidemiology. According to Dr. Cramer, there have been nineteen *published* case-control studies addressing the talc and ovarian cancer association since 1982.⁹ Docket 148-1 at 5, 20-21. Thus, the technique of using a case-control study to assess the association between talc use and ovarian cancer has been both tested and subjected to peer review.

Defendants are quick to note that Dr. Cramer's *specific findings* have not been tested or peer reviewed, specifically pointing to Dr. Cramer's categorization that allowed for a determination of the "[a]ssociation between genital talc use

⁷ The court has already discussed whether the expertise was developed for litigation or naturally flowed from the expert's research and found that it weighs in favor of admission. *Polski*, 538 F.3d at 839.

⁸ "In case-control studies, the researcher begins with a group of individuals who have a disease (cases) and then selects a similar group of individuals who do not have the disease (controls). The researcher then compares the groups in terms of past exposures. If a certain exposure is associated with or caused the disease, a higher proportion of past exposure among the cases than among the controls would be expected." Reference Manual on Scientific Evidence 559 (3d ed. 2011), *available at* 2011 WL 7724261, *6.

⁹ In other words, the technique of using a case-control study to analyze the association between talc use and genital cancer is generally accepted in the scientific community, even if the results of Dr. Cramer's specific study are outliers.

and ovarian cancer among non-Jewish serous invasive cases and controls without a family history of ovarian or early onset breast cancer, stratified by menopausal status.” Docket 148-1 at 17. This is mostly an attack on the results and not the methodology, and as a result goes to the weight to be given to the evidence and not its admissibility. Even if one were to consider defendants’ argument an attack on Dr. Cramer’s methodology, their argument is unpersuasive. First, although Dr. Cramer’s specific categorization has not been tested, there is no reason why testing cannot occur using either Dr. Cramer’s data or alternative data. Second, as discussed above, Dr. Cramer is in the process of getting his findings published. Third, and perhaps most important, Dr. Cramer’s categorization was his attempt to connect his research with the facts of the case. His technique makes sense under the facts of this case because it shows the odds ratio of a woman in Berg’s position.

Defendants criticize Dr. Cramer’s choice to exclude menopausal, non-Jewish women who do not have a history of ovarian or early onset breast cancer. But as Dr. Cramer explains, this decision was made because Berg is not Jewish, was premenopausal at the time of her diagnosis, and did not have a history of ovarian or early onset breast cancer.

Moreover, Dr. Cramer’s categorization is also a recognition of alternative causes of ovarian cancer. As Dr. Cramer points out in his report, women who are Jewish or have a history of breast or ovarian cancer are at an increased risk

for ovarian cancer. Berg is neither Jewish nor has a history, family or personal, of breast or ovarian cancer. Additionally, she tested negative for the full panel of BRCA1 and BRCA2 mutations—additional factors that increase one’s risk for ovarian cancer.

Lastly, defendants argue that Dr. Cramer’s theory of biological plausibility¹⁰ is unreliable, making his ultimate conclusions equally as unreliable. Dr. Cramer s two models of biological plausibility. One model relies on the assertion that talc induces inflammation, down regulates immunity, and enhances ovarian tumor development. The second model theorizes that talc’s inflammatory properties lead to dysregulation of immunity that would otherwise help suppress cancerous cells. Defendants assert that neither of these models has been proven. But defendants have not shown that either model is undoubtedly incorrect. In epidemiology, the “saliency of [biological plausibility] varies depending on the extent of scientific knowledge about the cellular and subcellular mechanisms through which the disease process works.” Reference Manual on Scientific Evidence 605 (3d ed. 2011), *available at* 2011 WL 7724261, *30. At times, “mechanism explanations are merely hypothesized—although hypotheses are sometimes accepted” in showing

¹⁰ Biological plausibility is the “[c]onsideration of existing knowledge about human biology and disease pathology to provide a judgment about the plausibility that an agent causes a disease.” Reference Manual on Scientific Evidence 620 (3d ed. 2011), *available at* 2011 WL 7724261, *38.

exposure can cause a disease. *Id.* Furthermore, Berg’s toxicologist expert, Dr. Rosenthal, is prepared to offer additional support for Dr. Cramer’s models of biological plausibility. Thus, Dr. Cramer’s biological plausibility models are not so fundamentally unsupported that they fail to assist the jury. *Sappington*, 512 F.3d at 448.

After a careful review of the record, the court concludes that Dr. Cramer’s expert testimony is reliable. Defendants can certainly attack his testimony at trial. *See Kuhn*, 686 F.3d at 625 (“Vigorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”). But his testimony will not be precluded based on the arguments that defendants put forward.

II. Dr. Gary Rosenthal

Dr. Rosenthal is prepared to offer expert testimony on the issue of “whether talc can be considered an immunotoxic¹¹ agent and the relevance of this to the biological plausibility of talc as an agent capable of causing ovarian cancer.” Docket 144-1 at 3. Defendants argue that Dr. Rosenthal is not qualified to offer his expert opinion and that his opinion is unreliable.¹²

¹¹ Immunotoxicology is a “branch of toxicology concerned with the effects of toxic agents on the immune system.” Reference Manual on Scientific Evidence 682 (3d ed. 2011), *available at* 2011 WL 7724262, *27.

¹² The court assumes, for purposes of this motion, that Dr. Rosenthal’s testimony is relevant.

A. Qualifications

“A witness can be qualified as an expert by knowledge, skill, experience, training or education, and it is the responsibility of the trial judge to determine whether a particular expert has sufficient specialized knowledge to assist jurors in deciding the specific issues in this case.” *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2011) (internal quotations omitted). “The relative skill or knowledge of an expert goes to the weight of that witness’s testimony, not its admissibility.” *Loudermill v. Dow Chemical Co.*, 863 F.2d 566, 569 (8th Cir. 1988).

Dr. Rosenthal received his Ph.D. in environmental medicine from New York University. He has been certified as a toxicologist by the American Board of Toxicology since 1990. His research includes the study of the toxicity of various agents on the immune system, including mineral dusts. He has also studied causative and preventative measures of inflammation and cancer.

Defendants argue that because Dr. Rosenthal has no experience specifically with talc or ovarian cancer, he is not qualified. Such a narrow view of an expert’s qualifications is not required under Rule 702. “Rule 702 only requires that an expert possess knowledge, skill, experience, training, or education sufficient to ‘assist’ the trier of fact, which is satisfied where expert testimony advances the trier of fact’s understanding to any degree.” *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (internal quotations

omitted). Dr. Rosenthal has experience studying the toxicity of mineral dust on the immune system. His expert testimony addresses whether talc can be considered an immunotoxic agent. Further, Dr. Rosenthal has experience studying the causative and preventative measures of inflammation and cancer. His expert testimony also addresses the biological plausibility of talc as an agent capable of causing ovarian cancer. Thus, the court finds that Dr. Rosenthal's qualifications are sufficient to assist the trier of fact in deciding the issues in this case.

B. Reliability

Dr. Rosenthal's expert report offers the following conclusions: (1) talc has immunotoxic¹³ potential; (2) it is biologically plausible that talc-mediated neoplastic events¹⁴ can be evoked through various mechanisms; (3) talc can translocate from the vagina, cervix, or fallopian tube to the ovary; (4) it is biologically plausible that Berg's daily talc use for over 30 years led to chronic inflammation in target tissues; (5) neoplastic events related to chronic inflammation and/or immune modulation would likely have been elicited in

¹³ Immunotoxic means that the agent in question exerts toxicity toward the immune system or its components.

¹⁴ A neoplastic event is a pathologic process that results in the formation and growth of abnormal tissue that grows by cellular proliferation more rapidly than normal and continues to grow after the stimuli that initiated the new growth cease. Stedman's Medical Dictionary 1288 (28th ed. 2006).

Berg; and (6) the foregoing would have played a role in disease processes leading to Berg's ovarian cancer. Docket 144-1 at 11.

Defendants argue that Dr. Rosenthal's biologically plausible opinions are merely speculative, untested, and unreliable. An examination of Dr. Rosenthal's methods is required to determine whether defendants' arguments have merit.

In reaching his conclusions, Dr. Rosenthal first addresses talc's physicochemical aspects. Docket 144-1 at 5. He asserts that talc's "poorly-soluble particulate nature" is significant because it allows talc "to be taken up by cells of the immune system . . . and transported to other parts of the body[.]" *Id.* He notes that talc shares this property with "other members of the mineral dust family, including silicates and asbestos." *Id.* He further notes that "an extensive literature exists showing that similar to asbestos and other mineral dusts, exposure to talc can result in cellular toxicity." *Id.* (citing published studies).

Dr. Rosenthal next addresses the biological evidence that supports his conclusions. He first asserts that the immune consequences of talc being "taken up" by cells "depends on the fate(s) of the cell and the engulfed talc particle." *Id.* at 6. Some fates result in the recruitment of other immune cells (because the body recognizes talc as a foreign particle) while others lead to an injury that

causes unique structures such as Giant cells¹⁵ and granulomas.¹⁶ *Id.* (citing published studies that show Giant cells and granulomas have been seen in response to talc exposure). Alternatively, the talc particle may be taken up by cells through the process of endocytosis.¹⁷ Any of these “fates” may “play some part in the response to mineral dust deposition on mucosal surface and would be associated with measures of inflammation[.]” *Id.* at 7. Dr. Rosenthal notes that several “studies show markers of inflammation following talc exposure, including intravaginal delivery.” *Id.* (citing several published articles).

To further support his opinions, Dr. Rosenthal discusses studies that show how talc can affect the immune system. He notes several studies that show talc induces granulomas in a variety of different organs. He then cites an animal study that found talc-induced granulomas resulted in deficient cellular immune functions that “have been noted to precede cancer in man.” *Id.* at 7. After discussing additional studies, Dr. Rosenthal generalizes that talc causes

¹⁵ Giant cells granuloma is a “nonneoplastic lesion characterized by a proliferation of granulation tissue containing numerous multinucleated giant cells[.]” Stedman’s Medical Dictionary 832 (28th ed. 2006).

¹⁶ Granuloma is a “[t]erm applied to nodular inflammatory lesions[.]” Stedman’s Medical Dictionary 831 (28th ed. 2006). “Granuloma formation is a special type of immune response to foreign agents, where the body produces a collection of immune and related cells in an attempt to wall off a foreign agent that has resisted digestion.” Docket 144-1 at 7.

¹⁷ Endocytosis is the “[i]nternalization of substances from the extracellular environment through the formation of vesicles formed from the plasma membrane.” Stedman’s Medical Dictionary 640 (28th ed. 2006).

two biologic responses—immune system suppression and inflammation—both of which have been found to be associated with cancer. *Id.* at 8-10. Moreover, he notes that the “intimate relationship between talc, inflammation, phagocytic cells,¹⁸ and ovary-derived chemotactic factors¹⁹ provides a mechanistic connection for talc translocation to the ovary where it can alter tissue homeostasis.” *Id.* at 9.

To summarize, Dr. Rosenthal’s report essentially provides that talc particles that are applied in the perineal area can move to the ovaries where they can be problematic for immune cells by causing chronic inflammation and/or immunity suppression. Chronic inflammation and immunity suppression have been shown to play roles in disease processes that lead to cancer. Based on Berg’s thirty-plus years of perineal exposure to talc, it is likely that she would have experienced such chronic inflammation and/or immunity suppression in her ovaries, thus playing a “role in disease processes leading to her ovarian cancer.” *Id.* at 11. Dr. Rosenthal relied on several published scientific articles as well as his own experience in immunotoxicology to form his conclusions.

¹⁸ Phagocytic cells are cells that can ingest bacteria, foreign particles, and other cells. Stedman’s Medical Dictionary 1470 (28th ed. 2006).

¹⁹ Chemotactic factors are factors that cause movement of cells in response to chemicals, whereby the cells are attracted or repelled by substances exhibiting chemical properties. Stedman’s Medical Dictionary 358 (28th ed. 2006).

Defendants attack Dr. Rosenthal's opinion from several perspectives. First, defendants challenge Dr. Rosenthal's comparison of talc with other mineral dusts, arguing that he is not qualified to discuss the relevant properties of the three mineral dusts. The main assertion that Dr. Rosenthal makes, however, is that talc, asbestos, and silica all have poorly-soluble particulate natures that encourage uptake by immune cells. It is this property, he opines, that would cause the three mineral dusts to act similar from an immunotoxicology perspective. *See, e.g., Reference Manual on Scientific Evidence* 664 (3d ed. 2011) (noting toxicologists often compare the structures of different compounds to infer toxicity). Dr. Rosenthal only relies on *one* physical property that the three substances share. Defendants urge the court to require Dr. Rosenthal to be an expert on *all* physicochemical properties of each substance if he is to compare any of them. Such expansive expertise, however, is not required. If defendants have issue with the factual basis for his comparisons, they are welcome to challenge it at trial, but such a challenge goes to the weight to be given to the evidence, not its admissibility. *Bonner*, 259 F.3d at 929 ("[T]he factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility.").

Second, defendants argue that Dr. Rosenthal's reference to historic accounts of asbestos in cosmetic talc is unreliable. Regardless of its reliability, the court finds this part of Dr. Rosenthal's opinion to be irrelevant. Berg has not

alleged that asbestos was in the talc that allegedly caused her ovarian cancer. Instead, she argues that the talc itself caused her ovarian cancer. Thus, any reference to historic accounts of asbestos in cosmetic talc is irrelevant and is also likely to confuse the jury. As a result, Dr. Rosenthal is precluded from testifying about historic accounts of asbestos in cosmetic talc.

Third, defendants take issue with Dr. Rosenthal's assertions relating to cellular toxicity. The general crux of defendants' arguments deal with the factual basis of the opinion and not the methodology. Further, defendants misinterpret Dr. Rosenthal's opinion. When disputing Dr. Rosenthal's claim that talc causes cellular toxicity, defendants argue that cellular toxicity is a general term not necessarily related to cancer. Nowhere in Dr. Rosenthal's expert report does he make the assertion that all cellular toxicity causes cancer. Thus, defendants' argument lacks merit.

Fourth, defendants argue that Dr. Rosenthal's references to metallic components in talc make his entire opinion unreliable, noting his deposition testimony in which he states that the "combination of these compounds together in the context of talc have not been studied in a detailed way[.]" Docket 144-2 at 14. The court agrees that Dr. Rosenthal's reference that he "would not completely dismiss a potential role for contaminating immunotoxic metals" is an unreliable statement because Dr. Rosenthal did not provide an adequate basis in science to support it. Nevertheless, this statement is a small part of his

report and has little or nothing to do with the rest of his expert opinion. Thus, his references to metallic components do not make his entire opinion unreliable.

Fifth, defendants attack Dr. Rosenthal's efforts to show biologic plausibility. They argue that because Berg's tissues did not indicate that the specific mechanisms that Dr. Rosenthal offered were present, his testimony is irrelevant.²⁰ The court disagrees and finds that Dr. Rosenthal's offering of mechanisms that provide biologic plausibility to Berg's claim that talc caused her ovarian cancer are relevant.²¹

Sixth, defendants argue that Dr. Rosenthal's opinion should be excluded because of his word choices in his report. The court will not entertain such a meritless objection.

Defendants' seventh challenge is similar to its third. They argue that because one of the mechanisms (TNF-alpha²²) that Dr. Rosenthal offers has not been conclusively proven to cause cancer, it is unreliable. This again misstates Dr. Rosenthal's report. The report asserts that talc has been shown to cause

²⁰ Defendants' argument goes to the sufficiency of specific causation rather than admissibility. This argument is more properly addressed as part of the motion for summary judgment.

²¹ If defendants had conclusive proof that the mechanisms were not present, then such testimony would likely be irrelevant.

²² TNF-alpha stands for tumor necrosis alpha, which is a pleiotropic cytokine synthesized widely throughout the female reproductive tract. Stedman's Medical Dictionary 698 (28th ed. 2006).

inflammation through an increase in TNF-alpha. The report does not state that TNF-alpha causes cancer—the basis for defendants’ challenge.

Defendants’ eighth challenge attacks the factual basis for Dr. Rosenthal’s opinion. First, they argue that one of the studies he relied on is a case report. But their citation to *Glastetter v. Novartis Pharmaceuticals Corporation*, 252 F.3d 986 (8th Cir. 2001), is not dispositive. *Glastetter* simply states that “causal attribution based on case studies must be regarded with caution.” 252 F.3d at 990. Here, Dr. Rosenthal is not using case studies as the entire foundation for his opinions, but just as one piece of the puzzle. Further, defendants argue that Dr. Rosenthal’s admission that there is a scientific debate about whether talc is immunosuppressive precludes his testimony. This admission does not make his opinion unreliable. *See Kuhn*, 686 F.3d at 625 (“Proponents of expert testimony need not demonstrate that the assessments of their experts are correct, and trial courts are not empowered to determine which of several competing scientific theories has the best provenance.”) (internal quotation omitted).

Defendants’ ninth challenge is not actually a challenge at all. Instead, defendants simply reference various statements made by Dr. Rosenthal in relation to Dr. Cramer’s theories.

Tenth, defendants take issue with Dr. Rosenthal’s proffer that the immunosuppressive effects of asbestos may contribute to malignancy by decreasing natural killer cells. Dr. Rosenthal offers this statement to support

his conclusion that substances that have immunosuppressive effects play a role in the disease processes leading up to cancer development. He does not assert, as defendants suggest, that talc exposure decreases natural killer cells. Again, defendants' misstatement of Dr. Rosenthal's opinion makes their objection meritless.

Defendants' eleventh challenge shares many of the shortcomings as their previous challenges. Defendants muddle sufficiency with admissibility, arguing that Berg's medical records did not show evidence of inflammation and thus any theory of inflammation is irrelevant. They challenge the factual basis of Dr. Rosenthal's opinion, claiming his interpretation of various animal studies makes his opinion unreliable. Lastly, they take Dr. Rosenthal's reluctance to definitively state that talc exposure causes ovarian cancer to mean that his opinions are speculative and unreliable. Dr. Rosenthal's report, however, does not assert that talc exposure causes ovarian cancer. Instead, Dr. Rosenthal's report states that Berg's talc exposure "would have played a role in disease processes leading to her ovarian cancer." Docket 144-1 at 11.

In summary, the court finds that the majority of defendants' challenges to Dr. Rosenthal's expert testimony are unpersuasive. In making his ultimate conclusions, Dr. Rosenthal relied on his own expertise in the field of toxicology, his past research, and several other published scientific studies. Any gaps or limitations in Dr. Rosenthal's reasoning can be presented to the jury. *See Kuhn*,

686 F.3d at 632 (“The studies’ limitations may be presented to the jury, and [the expert’s] reliance on the studies may be tested through the traditional means of cross examination and presentation of contrary evidence.”). Indeed, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596.

III. Dr. John Godleski

Dr. Godleski reviewed histopathological²³ slides taken from Berg following her diagnosis of ovarian cancer using advanced microscopic methodologies. In his review of twenty-six slides, Dr. Godleski found three particles of talc. He asserts that his findings indicate that talc was present in Berg’s ovary tumor. Dr. Godleski opines that the talc found in Berg’s tissues “is evidence for a causal link between the presence of talc and the development of [her] ovarian cancer.” Docket 141-1 at 4.

Defendants argue that Dr. Godleski is unqualified and that his opinions are irrelevant and unreliable.

A. Qualifications

Dr. Godleski is the head of Pulmonary Pathology at Brigham and Women’s Hospital, a major teaching hospital of Harvard Medical School. He also

²³ Histopathology is the science or study dealing with the cytologic and histologic structure of abnormal or diseased tissue. Stedman’s Medical Dictionary 893 (28th ed. 2006).

leads a research group at the Harvard School of Public Health. He earned his medical degree from the University of Pittsburgh School of Medicine where he did research using electron microscopy. He has published more than 140 papers related to pulmonary pathology including a number using analytical electron microscopy. He is a “recognized expert whose opinion is sought by pathologists from other hospitals in the diagnosis of foreign material in tissues throughout the body using scanning electron microscopy and energy dispersive X-ray analyses.” Docket 141-1 at 2.

Defendants note that Dr. Godleski’s background does not include determining the causes of ovarian cancer. They argue that Dr. Godleski has done limited research on the relationship between talc and ovarian cancer, that his knowledge of the causes of ovarian cancer is limited, and that he is not an epidemiologist. On the other hand, defendants do not dispute that Dr. Godleski is an expert at identifying foreign particles in human tissue. Because his testimony is limited to identifying foreign particles in human tissue, the court finds he is qualified to offer his expert opinion.

B. Relevancy

Defendants argue that Dr. Godleski’s opinions are irrelevant because he cannot tie the talc particles found in Berg’s tissues to defendants’ products. This argument goes to the sufficiency of the testimony, not the relevancy of it. Berg claims that talc from defendants’ products caused her ovarian cancer.

Certainly, testimony that establishes that talc particles were found in Berg's ovary tumor is relevant to this case.

C. Reliability

Defendants' reliability arguments are based on a mischaracterization of Dr. Godleski's expert opinion. Their arguments suggest that Dr. Godleski is opining that the talc particles he found caused Berg's ovarian cancer.

Dr. Godleski's opinion stops well short of such a conclusion. His report notes that "the talc found in this case is evidence for a causal link between the presence of talc and the development of [Berg's] ovarian cancer." Docket 141-1 at 4. His opinion merely states the obvious: the talc found in Berg's tissues is evidence in this case.

Defendants again argue that Dr. Godleski is required to rule out alternative causes. Because Dr. Godleski is not opining that talc was the cause of Berg's ovarian cancer through a differential diagnosis, he need not rule out other potential causes of her cancer. The fact that he found particles other than talc goes to the sufficiency of his testimony. The remainder of defendants' arguments are based on their mischaracterization of Dr. Godleski's opinions and will not be addressed. Therefore, Dr. Godleski's expert testimony will not be excluded.

IV. Dr. David R. Lenorovitz and Dr. Edward E. Karnes

Dr. Lenorovitz and Dr. Karnes are prepared to provide expert testimony “addressing certain forensic human factors and warnings issues.”²⁴ Docket 146-3 at 3. Defendants argue that the expert report goes far beyond the boundaries applicable to human factors experts. In addition, defendants argue that any proposed testimony that is related to human factors is unreliable.

A. Qualifications

The court begins its evaluation by addressing the experts’ qualifications. Dr. Lenorovitz has 44 years of professional experience as a human factors engineer, ergonomist, and cognitive psychologist. He received his Ph.D. in human factors engineering from the State University of New York and is certified as a professional ergonomist by the Board of Certification in Professional Ergonomics. He has spent the last six years as a forensic human factors consultant with a special emphasis on warnings systems design, development, and warnings adequacy evaluation.

Dr. Karnes has 50 years of professional experience as a human factors professional. He received his Ph.D. in experimental psychology from Temple University and is board-certified. He has served as a human factors consultant for plaintiffs and defendants in several different legal cases. The majority of his

²⁴ According to Berg, forensic human factors and warnings is the “multidisciplinary field examining how humans interact with the world around them.” Docket 173 at 1.

research has concerned the development of warnings and user understanding of safety issues associated with the use of consumer and industrial products.

Both experts are qualified to render an expert opinion within their field.

B. Defendants' Challenges

Defendants first take issue with any attempt by the experts to offer testimony regarding defendants' intent as well as testimony regarding defendants' purported lobbying efforts. *See, e.g.*, Docket 146-3 at 14 ("The defendants have knowingly decided to ignore the hazard present in their products."); Docket 146-3 at 5 ("The defendants collaborated and joined forces with other 'talc-interested parties' to pool resources and fund . . . programs intended to . . . defeat any research study[.]"). Both Dr. Karnes and Dr. Lenorovitz admit that the basis for their opinions about defendants' intent and lobbying efforts comes from "reading the documents that were provided." Docket 146-2 at 20; 22. "Where the subject matter is within the knowledge or experience of lay people, expert testimony is superfluous." *Ellis v. Miller Oil Purchasing Co.*, 738 F.2d 269, 270 (8th Cir. 1984). There is no reason why the jury cannot review the same documents and form their own opinions about defendants' intent and lobbying efforts. Thus, Drs. Karnes and Lenorovitz are precluded from offering an expert opinion about defendants' intent or lobbying efforts because such testimony would be superfluous.

Next, defendants seek to preclude Drs. Karnes and Lenorovitz from testifying about any legal conclusions, e.g., any duties that defendants owed to Berg. Under South Dakota law, whether a duty exists is a question of law. *Bland v. Davison Cnty*, 507 N.W.2d 80, 81 (S.D. 1993). Any expert testimony on a legal conclusion will not assist the trier of fact and is thus inadmissible. *United States v. Wells*, 63 F.3d 745, 753 (8th Cir. 1995) (“[I]nstruction on the law is the function of the court, not a defense expert.”), *rev’d on other grounds*, 519 U.S. 482 (1997); *Peterson v. City of Plymouth*, 60 F.3d 469, 475 (8th Cir. 1995) (“The legal conclusions were for the court to make. It was an abuse of discretion to allow the testimony.”). Thus, Drs. Karnes and Lenorovitz are precluded from testifying about any duties or responsibilities that defendants allegedly owed to Berg.

Defendants also move the court to preclude any testimony Drs. Karnes and Lenorovitz may offer that is outside their expertise, such as the medical risks of ovarian cancer, whether talc is hazardous, and whether there is a feasible alternative product. “An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed.” Fed. R. Evid. 702. Thus, Drs. Karnes and Lenorovitz can form their opinions based on the testimony of other experts in this case. But Drs. Karnes and Lenorovitz cannot make unsupported statements that are outside of their field of expertise. *See Anderson v. Raymond Corp.*, 340 F.3d 520, 523 (8th Cir. 2003) (noting that

the district court did not abuse its discretion in deciding that an expert could not testify about matters outside of his expertise). In addition, the court need not admit cumulative evidence. Fed. R. Evid. 403. Any detailed description of testimony provided by Berg's other experts regarding the medical risks of ovarian cancer, whether talc is hazardous, and whether there is a feasible alternative product would certainly be cumulative because Drs. Karnes and Lenorovitz are not capable of offering their novel opinions in such areas as they are not qualified to do so. Therefore, the testimony of Drs. Karnes and Lenorovitz regarding these areas must be limited. For purposes of their testimony, Drs. Karnes and Lenorovitz may only "assume" that ovarian cancer has medical risks, talc is hazardous, and there is a feasible alternative product.²⁵ They cannot, however, go into detail on any of these subjects.

More generally, Berg asserts that Drs. Karnes and Lenorovitz were designated (1) to ascertain if talc posed a hazard to the populace; (2) to determine whether the hazard was open and obvious to a reasonable user; (3) to determine if there was a feasible way to place a warning on the talc product; and (4) to determine if there was a financially and technically reasonable alternative to talc. Docket 173 at 2. As discussed above, Drs. Karnes and

²⁵ This assumes that plaintiff will present evidence that there is a feasible alternative product.

Lenorovitz are not qualified to provide an opinion on whether talc is hazardous to the populace or whether there is a financially reasonable alternative to talc.

Moreover, Drs. Karnes and Lenorovitz cannot assist the jury on the issue of whether the alleged hazard was open and obvious to a reasonable user. The basis for Drs. Karnes and Lenorovitz concluding that the alleged hazard was not open and obvious is based solely on the fact that Berg, Dr. Karnes, and Dr. Lenorovitz were not aware of the hazard prior to this litigation. A jury can rely on its own common sense and experiences in forming its conclusion on whether the alleged hazard was open and obvious.

Therefore, the testimony of Drs. Karnes and Lenorovitz will be limited to whether there was a feasible way to place a warning on defendants' products.²⁶ The court will now turn to defendants' summary judgment motion.

SUMMARY JUDGMENT LEGAL STANDARD

Summary judgment is appropriate if the movant "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party can meet this burden by presenting evidence that there is no dispute of material fact or that the nonmoving party has not presented evidence to support an element of her

²⁶ After reviewing the remainder of the report in light of the extensive limitations discussed above, the court finds that any additional proposed testimony outside of the issue of placing a warning on the product is not admissible because it is either cumulative or outside the expertise of Drs. Karnes and Lenorovitz.

case on which she bears the ultimate burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). “The nonmoving party may not ‘rest on mere allegations or denials, but must demonstrate on the record the existence of specific facts which create a genuine issue for trial.’” *Mosley v. City of Northwoods, Mo.*, 415 F.3d 908, 910 (8th Cir. 2005) (quoting *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995)).

Summary judgment is precluded if there is a dispute in facts that could affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). For purposes of a summary judgment motion, the court views the facts and the inferences drawn from such facts “in the light most favorable to the party opposing the motion.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

Because this is a diversity action, the court applies the law of the state in which it sits. *Prudential Ins. Co. of Am. v. Kamrath*, 475 F.3d 920, 924 (8th Cir. 2007). Thus, South Dakota law applies to Berg’s claims.²⁷

ANALYSIS

Defendants move for summary judgment on three grounds: (1) Berg’s experts do not present admissible evidence of causation and have failed to rule out other potential causes; (2) there is no evidence that would impose upon

²⁷ The parties do not dispute that South Dakota law applies.

defendants a duty to warn; and (3) Berg cannot demonstrate that defendants' failure to warn caused her ovarian cancer.

I. Evidence of Causation

Defendants argue that Berg has not presented admissible evidence of causation and thus all of her claims must fail. To survive summary judgment, Berg must present evidence beyond unsupported conclusions and speculative statements that defendants' products caused her injuries. *Burley v. Kytect Innovative Sports Equip., Inc.*, 737 N.W.2d 397, 407-10 (S.D. 2007). Expert testimony is ordinarily required to establish causation in a products liability action, particularly in a toxic tort action. *Id.*; see also *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 450 (8th Cir. 2010) ("To succeed in her claims, [plaintiff] needed to present expert testimony showing that the [substance] could have caused [the] injuries and that it did in fact cause those injuries.").

The majority of defendants' arguments rely on the assumption that the court would grant their motions to exclude expert testimony analyzed above. But because the court found that the majority of the expert testimony offered by Berg is admissible, most of defendants' arguments are moot. The court will nonetheless evaluate the admissible evidence that Berg has put forth to ensure that she has met her burden of creating a genuine issue of fact on the causation element.

As a preliminary matter, Berg asserts, and defendants do not dispute, that she began using talc in her genital area in 1975. She claims that the talc came from defendants' products—"Johnson's Baby Powder" and "Shower to Shower"—and that her use continued until 2007. It is undisputed that Berg was diagnosed with ovarian cancer in December of 2006.

Berg has put forth admissible expert testimony to support her claim that defendants' products caused her ovarian cancer. First, Dr. Cramer, an epidemiologist, opines generally that talc use in the genital area has a strong causal association with ovarian cancer. *See Glastetter*, 252 F.3d at 992 (noting that epidemiological evidence can assist in establishing causation). He goes further to opine that Berg's frequent application of talc to her genital area was "the major cause of her invasive serous ovarian cancer[.]" Docket 148-1 at 18. In forming his opinions, Dr. Cramer relied on various facts: Berg was pre-menopausal when she was diagnosed; she has no personal or family history of breast or ovarian cancer; she is not Jewish; she tested negative for the full panel of BRCA1 and BRCA2 mutations; and the odds ratio for someone with similar characteristics is 3.53.

Second, Dr. Rosenthal, a toxicologist, provides biologic plausibility to Dr. Cramer's opinions. *See Marmo*, 457 F.3d at 758 ("[A] toxicologist may testify that exposure to a chemical caused a person's symptoms and injuries."). He asserts that talc has immunotoxic potential and can evoke neoplastic events,

which may lead to ovarian cancer. Further, he claims that it is biologically plausible that Berg's frequent application of talc led to chronic inflammation and/or immune modulation of tissues and cells in her ovaries. Thus, he concludes that Berg's frequent genital application of talc "played a role in disease processes leading to her ovarian cancer." Docket 144-1 at 11.

Third, Dr. Godleski, an expert in microscopy, provides evidence that talc was actually present in the tissues that were removed from Berg's ovaries and fallopian tubes following her diagnosis. Lastly, Berg claims that had she known of any dangers involved in applying talc to her genital area, she would not have done so.

Defendants urge the court to grant summary judgment because Berg has not ruled out other potential causes of her ovarian cancer. But Berg is not required to "eliminate all other possible explanations of causation[.]" *Burley*, 737 N.W.2d at 407. She needs only to "set forth sufficient evidence establishing a causal connection between the [defendants' product] and the resulting injury." *Id.* The court finds that she has done so here. Determining the weight of the evidence Berg has put forth is an issue for the jury.

II. Duty to Warn

Defendants argue that Berg cannot move forward with her failure to warn claims because she has not established the existence of a duty to warn. The

court must separate Berg's failure to warn claims to address defendants' argument.

A. Strict Liability Failure to Warn

Defendants argue that they did not owe Berg a duty to warn because their product is not dangerous. "The issue under strict liability is whether the manufacturer's failure to adequately warn rendered the product unreasonably dangerous without regard to the reasonableness of the failure to warn judged by negligence standards." *Peterson v. Safway Steel Scaffolds Co.*, 400 N.W.2d 909, 912 (S.D. 1987). "[K]nowledge of the potential risk is imputed to the manufacturer." *Id.* Thus, defendants cannot defend "on grounds that, at the time of production, [they] neither knew nor could have known of the risk." *Id.* Thus, if Berg can establish at trial that a "danger existed associated with a foreseeable use of [defendants'] product," the duty to warn element is automatically satisfied for purposes of her strict liability failure to warn claim. *Burley*, 737 N.W.2d at 409.

B. Negligent Failure to Warn

To establish liability for negligent failure to warn, Berg must show, among other things, that defendants "knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner." *Id.* at 410. Defendants argue that there was and still is no duty to warn because there lacks any substantial evidence that

their products are dangerous. Additionally, defendants argue that any evidence that Berg puts forth that allegedly shows dangers associated with defendants' products falls short of creating a duty to warn.

Defendants' arguments are premature at this time. Defendants are correct in stating that under South Dakota law "the existence of a duty is a question of law to be determined by the court." *Janis v. Nash Finch Co.*, 780 N.W.2d 497, 500 (S.D. 2010). But in a negligent failure to warn case, whether defendants owed Berg a duty to warn depends, first, on whether defendants' products are unreasonably dangerous. *See Burley*, 737 N.W.2d at 410 (requiring plaintiff to show that the "manufacturer knew or reasonably should have known that the product was dangerous"). Indeed, if defendants' products are not dangerous, no warning would be necessary. Whether defendants' products are unreasonably dangerous is a factual determination for the jury. *See Peterson*, 400 N.W.2d at 914 ("[I]ssues of reasonableness and foreseeability . . . are usually jury issues."). Thus, the court cannot make its legal determination of whether a duty existed until the jury has the opportunity to determine if the products are dangerous. *See Reiss v. Komatsu America Corp.*, 735 F. Supp. 2d 1125, 1146 (D.N.D. 2010) ("The existence of a duty to warn is generally a preliminary question of law for the court, but if the existence of a duty depends

upon factual determinations, their resolution must be resolved by the trier of fact.”).²⁸

III. Proximate Cause

Defendants also argue that Berg has failed to put forth sufficient facts to show that defendants’ failure to warn was the legal cause of her ovarian cancer. Defendants’ argument raises the issue of when the duty to warn arose. They claim that even if a duty to warn exists, such duty arose much later than 1975—the year Berg began dusting her perineum with talc. Thus, defendants argue, Berg cannot prove that defendants’ failure to warn was the legal cause of her cancer because the duty did not arise in time to prevent her cancer.

As discussed above, Berg’s strict liability claim does not necessitate the finding that a duty existed. Moreover, the issue of *whether* a duty ever existed must first be determined in order to ascertain *when* such a duty arose. Even so, Berg has put forth evidence that defendants were aware of the alleged dangers of talc as early as 1971. Thus, there is a material issue of fact as to whether defendants “knew or reasonably should have known that the product was dangerous” as far back as 1971. *See Burley*, 737 N.W.2d at 410.

²⁸ Defendants’ reliance on *Brech v. J.C. Penney Co.*, 698 F.2d 332, 334 (8th Cir. 1983), in support of their assertion that federal standards are relevant in determining if a duty to warn existed is misplaced. In review of District Court Judge Nichol’s factual findings from a bench trial, the Eighth Circuit stated that “[a]lthough evidence that the gown surpassed federal standards is not necessarily conclusive proof that the garment was not *unreasonably dangerous*, it is nevertheless evidence which the court can consider on the issue.” *Id.* (emphasis added).

In summary, Berg has put forth sufficient, admissible evidence to show that there exists genuine issues of material fact. Also, the court is unable to determine whether defendants owed Berg a duty to warn at this time. Thus, defendants' motion for summary judgment is denied.

CONCLUSION

Dr. Cramer's expert opinion is admissible because it was the product of reliable methodologies, and he was not required, as an epidemiologist, to rule out all alternative causes of Berg's ovarian cancer. The majority of Dr. Rosenthal's opinions are admissible because he is qualified to render such opinions, and he used reliable methodologies in forming his opinions.

Dr. Godleski's opinion is admissible because he is qualified, and the opinion is relevant and stems from reliable methodologies. Lastly, Dr. Lenorovitz and Dr. Karnes, as human factors experts, can only testify on the limited issue of whether there was a feasible way to place a warning on defendants' products.

Moreover, Berg has put forth sufficient evidence to show that there exists genuine issues of material fact that preclude summary judgment. Furthermore, the court is unable to determine whether defendants owed Berg a duty to warn at this time. Accordingly, it is

ORDERED that defendants' motion to exclude the testimony of Dr. Godleski (Dockets 140 & 153) is denied.

IT IS FURTHER ORDERED that defendants' motion to exclude the testimony of Dr. Rosenthal (Dockets 143 & 156) is granted in part and denied in part.

IT IS FURTHER ORDERED that defendants' motion to exclude the testimony of Dr. Lenorovitz and Dr. Karnes (Dockets 145 & 155) is granted in part and denied in part.

IT IS FURTHER ORDERED that defendants' motion to exclude the testimony of Dr. Cramer (Docket 147 & 151) is denied.

IT IS FURTHER ORDERED that defendants' motion for summary judgment (Docket 149) is denied.

Dated April 12, 2013.

BY THE COURT:

/s/ Karen E. Schreier

KAREN E. SCHREIER
UNITED STATES DISTRICT JUDGE

Exhibit 131

**IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI**

MICHAEL BLAES on behalf of SHAWN)	
BLAES, Deceased,)	
SAVANNA CREWS on behalf of)	
ANGELA DAWN HERSHMAN,)	Cause No. 1422-CC09326-01
Deceased,)	
DARLENE EVANS on behalf of ERON)	Division 10
EVANS, Deceased,)	
)	
Plaintiffs,)	
)	
v.)	
)	
JOHNSON & JOHNSON, et al.,)	
)	
Defendants.)	

FILED
JUN 12 2017
22ND JUDICIAL CIRCUIT
CIRCUIT CLERK'S OFFICE
BY _____ DEPUTY

ORDER

This cause is now before the Court on: (1) Motions for Summary Judgment filed by Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc.; and (2) Motions to Exclude the Testimony of Dr. Colditz, Dr. Cramer, Dr. Godleski, Dr. Ness, Dr. Omiecinski, Dr. Siemiatycki, Dr. Plunkett, Dr. Rosenthal, Dr. Chobanian and Mr. Steinberg filed by Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc.; and (3) Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc. Motions to Transfer Venue or Continue the June 5, 2017 Trial Date Based on Jury Pool Taint.

The Court now rules as follows:

Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc.'s, Motions for Summary Judgment are **DENIED**.

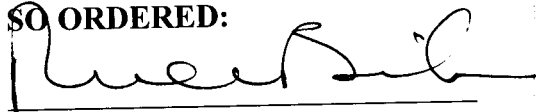
Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc.'s Motions to Exclude the Testimony of Dr. Colditz, Dr.

ENTERED
JUN 12 2017
TSJ

Cramer, Dr. Godleski, Dr. Ness, Dr. Omiecinski, Dr. Siemiatychi, Dr. Plunkett, Dr. Rosenthal, Dr. Chobanian and Mr. Steinberg are **DENIED**.

Defendant Johnson & Johnson and Defendant Johnson & Johnson Consumer, Inc.'s and Defendant Imerys Talc America, Inc.'s Motions to Transfer Venue or Continue the June 5, 2017 Trial Date Based on Jury Pool Taint is **DENIED**.

SO ORDERED:

A handwritten signature in black ink, appearing to read 'Rex M. Burlison', written over a horizontal line.

Rex M. Burlison
Circuit Judge
Division 10

Dated: 6/12/2017

Exhibit 132

IN THE STATE COURT OF FULTON COUNTY
STATE OF GEORGIA

ANASTASIA BROWER, a minor, through her)	
legal guardian PAMELA RUSSELL, and)	
PAMELA RUSSELL, as the Executrix of the)	
Estate of Diane Brower, deceased,)	
Plaintiff,)	
)	
v.)	CIVIL ACTION FILE
)	NO. 16-EV-005534-E
)	
JOHNSON & JOHNSON, INC.; JOHNSON &)	
JOHNSON CONSUMER COMPANIES, INC.;)	
and IMERYS TALC AMERICA, INC.,)	
Defendants.)	

**ORDER ON JOHNSON DEFENDANTS' MOTIONS TO EXCLUDE THE
TESTIMONY OF DR. JAMES BARTER, DR. LAURA PLUNKETT, AND DR.
JOHN GODLESKI**

The matter is before the Court on Defendant Johnson & Johnson, Inc., and Johnson & Johnson Consumer Companies, Inc.'s ("Johnson Defendants") motions to exclude the expert testimony of various witnesses, filed on October 30, 2019.¹ Plaintiff filed responses in opposition to the motions to exclude on November 29, 2018.

The Daubert Standard

Trial courts act as gatekeepers in assessing an expert witness' qualifications to testify and the relevancy and reliability of that expert's testimony. Kumho Tire Co. v. Carmicheal, 526 U.S. 137, 141 (1999). Motions to exclude testimony of an expert witness are properly granted "where there is no circumstance under which the evidence under scrutiny is likely to be admissible at trial." Shiver v. Ga. & Fla. Railnet, Inc., 287 Ga. App. 828, 829 (2007) (quoting Gwinnett Co. v. Howington, 280 Ga. App. 347 (2006)). Expert scientific or technical testimony is admissible only if it is both relevant and reliable. Kumho Tire Co., at 137. The test for determining the reliability of expert testimony is flexible and the *Daubert* factors, such as testing, peer review, error rates, and

¹ While the motion was filed by the Defendants, Defendant Imerys Talc America, Inc., filed a notice of bankruptcy on February 13, 2019 and this Court entered an order reserving rulings on all pending motions filed by Defendant Imerys Talc America, Inc.

acceptability within relevant scientific or technical communities, “neither necessarily nor exclusively appl[y] to all experts or in every case.” *Id.*, at 142.

The determination of whether a witness is qualified to render an opinion as an expert is a legal determination for the trial court and is not disturbed by reviewing courts absent an abuse of discretion. *HNTB Ga., Inc., v. Hamilton-King*, 287 Ga. 641, 642 (2010); *Yount v. State*, 249 Ga. App. 563, 565 (2001). In considering the admissibility of expert testimony, a trial court should first consider whether the factors are reasonable measures of reliability in a given case before evaluating proffered expert testimony. *Kumho Tire Co.*, at 152. The Georgia Court of Appeals has identified the “two methods by which [a] plaintiff in a chemical exposure case may show specific causation in a manner that satisfies the *Daubert* standard: (1) ‘dose/response relationship’ or ‘threshold phenomenon;’ and (2) ‘differential diagnosis.’” *Shiver v. Ga. & Fla. Railnet, Inc.*, 287 Ga. App. 828 (2007)(quoting *Hardyman v. Norfolk & Western R. Co.*, 243 F3d 225, 263 (2001)). In *Hardyman*, the Sixth Circuit Court of Appeals noted that Plaintiff’s expert testified that “one simply could not quantify the level or dose of risk factors causative of [carpal tunnel syndrome] in a manner consistent with a dose/response relationship or threshold level.” *Hardyman*, at 262. The *Hardyman* Court likened carpal tunnel syndrome and its unknown dose/response relationship with exposure to toxic substances:

while precise information concerning the exposure necessary to cause specific harm to humans and exact details pertaining to the plaintiff’s exposure are beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans given substantial exposure and need not invariably provide the basis for an expert’s opinion on causation.

Hardyman, at 265-66(quoting *Westberry v. Gislaved Bummi AB*, 178 F.3d 257, 264 (4th Cir. 1999)).

Finally, a critical distinction exists between the admissibility of expert testimony and its credibility as determined by the trier of fact: “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596 (1993).

Dr. James Barter

Defendant moves the Court to limit the expert testimony of Dr. James Barter on the grounds that he failed to rule in Ms. Brower's use of Johnson & Johnson as a possible cause of her ovarian cancer and his failure to rule out other risk factors associated with cancer. Defendant's contentions go to the credibility of his testimony, not its admissibility. Daubert, *supra*. Accordingly, based upon review of the record and applicable law cited above, Defendants' motion to exclude the testimony of Dr. James Barter is DENIED.

Dr. Laura Plunkett

Defendant moves the Court to limit the expert testimony of Dr. Laura Plunkett on the basis that she does not have the requisite experience to testify about the causes of ovarian cancer, has never been a business executive or manager of product safety for a cosmetics company, and does not have legal training. A review of the record indicates that Dr. Plunkett has significant experience as a board certified pharmacologist and toxicologist. Accordingly, based upon the record as a whole and applicable law cited above, Defendants' motion to exclude the testimony of Dr. Laura Plunkett is DENIED.

Dr. John Godleski

Defendant moves the Court to exclude the expert testimony of Dr. John Godleski on the basis that his report fails to identify the methodology relied on in his conclusion. A review of the record indicates that Dr. Godleski's report details his methodology sufficiently in his report. Accordingly, based upon the record as a whole and applicable law cited above, Defendants' motion to exclude the testimony of Dr. John Godleski is DENIED.

SO ORDERED this 26th day of March, 2019.


Jane Morrison, Judge
FULTON COUNTY STATE COURT

Copies to Counsel via E-File Georgia.

Exhibit 134

Linda Loretz, Ph.D.

Page 379

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

-----x

IN RE JOHNSON & JOHNSON) MDL No.
TALCUM POWDER PRODUCTS) 16-2738 (FLW)(LHG)
MARKETING SALES PRACTICES,)
AND PRODUCTS LIABILITY)
LITIGATION)
)
THIS DOCUMENT RELATES TO)
ALL CASES)

-----x

V O L U M E I I

VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT
PERSONAL CARE PRODUCTS COUNCIL
by and through its Designated Representative,

LINDA LORETZ, Ph.D.

WASHINGTON, D.C.

MONDAY, OCTOBER 1, 2018

9:09 A.M.

Reported by: Leslie A. Todd

Linda Loretz, Ph.D.

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<p>1 Deposition of LINDA LORETZ, Ph.D., held at the 2 offices of: 3 4 5 SEYFARTH SHAW LLP 6 975 F Street, N.W. 7 Washington, DC 20004 8 9 10 11 12 Pursuant to notice, before Leslie Anne Todd, 13 Court Reporter and Notary Public in and for the 14 District of Columbia, who officiated in 15 administering the oath to the witness. 16 17 18 19 20 21 22 23 24 25</p>	<p>1 APPEARANCES (CONTINUED): 2 3 MICHELLE A. PARFITT, ESQUIRE 4 ASHCRAFT & GEREL, LLP 5 4900 Seminary Road, Suite 650 6 Alexandria, Virginia 22311 7 (703) 997-1774 8 9 NICHOLAS J. KOHRS, ESQUIRE 10 LUNDY, LUNDY, SOILEAU & SOUTH, LLP 11 501 Broad Street 12 Lake Charles, Louisiana 70601 13 (337) 439-0707 14 15 ON BEHALF OF PCPC AND THE WITNESS: 16 THOMAS T. LOCKE, ESQUIRE 17 SEYFARTH SHAW LLP 18 975 F Street, NW 19 Washington, DC 20004 20 (202) 463-2400 21 22 23 24 25</p>
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<p>1 APPEARANCES 2 3 ON BEHALF OF THE PLAINTIFFS: 4 CHRISTOPHER V. TISI, ESQUIRE 5 LEVIN PAPANTONIO THOMAS MITCHELL 6 RAFFERTY & PROCTOR, PA 7 316 S. Baylen Street, Suite 600 8 Pensacola, Florida 32502 9 (850) 436-6250 10 11 RICHARD M. GOLOMB, ESQUIRE 12 BENJAMIN ISSER, ESQUIRE 13 GOLOMB & HONIK, P.C. 14 1835 Market Street, Suite 2900 15 Philadelphia, Pennsylvania 19103 16 (215) 985-9177 17 18 TED MEADOWS, ESQUIRE 19 P. LEIGH O'DELL, ESQUIRE 20 RYAN BEATTIE, ESQUIRE 21 BEASLEY, ALLEN, CROW, METHVIN, PORTIS & 22 MILES, P.C. 23 218 Commerce Street 24 Montgomery, Alabama 36104 25 (334) 269-2343</p>	<p>1 APPEARANCES (CONTINUED): 2 3 ON BEHALF OF JOHNSON & JOHNSON DEFENDANTS: 4 KATHLEEN FRAZIER, ESQUIRE 5 SHOOK, HARDY & BACON, LLP 6 600 Travis Street 7 Suite 3400 8 Houston, Texas 77002-2926 9 (713) 227-8008 10 11 ON BEHALF OF THE IMERY'S DEFENDANTS: 12 JONATHAN F. DONATH, ESQUIRE 13 COUGHLIN DUFFY, LLP 14 350 Mount Kemble Avenue 15 Morristown, New Jersey 07962 16 (973) 267-0058 17 18 CATHERINE SLAVIN, ESQUIRE 19 GORDON & REES SCULLY MANSUKHANI, LLP 20 Three Logan Square 21 1717 Arch Street, Suite 610 22 Philadelphia, Pennsylvania 19103 23 (215) 717-4006 24 25</p>

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Linda Loretz, Ph.D.

<p style="text-align: right;">Page 384</p> <p>1 APPEARANCES (CONTINUED):</p> <p>2</p> <p>3 ON BEHALF OF PTI:</p> <p>4 JAMES W. MIZGALA, ESQUIRE</p> <p>5 TUCKER ELLIS, LLP</p> <p>6 233 South Wacker Drive</p> <p>7 Suite 6950</p> <p>8 Chicago, Illinois 60606-9997</p> <p>9 (312) 624-6307</p> <p>10</p> <p>11 ALSO PRESENT:</p> <p>12</p> <p>13 KATIE TUCKER (Paralegal - Beasley Allen)</p> <p>14 EMILY H. MANOSO, Staff Counsel, PCPC</p> <p>15 THOMAS F. MYERS, Staff Counsel, PCPC</p> <p>16</p> <p>17 DANIEL HOLMSTOCK (Videographer)</p> <p>18 JONATHAN VADERS (Technical Support)</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 386</p> <p>1 E X H I B I T S</p> <p>2 (Attached to transcript)</p> <p>3 LORETZ DEPOSITION EXHIBITS PAGE</p> <p>4 No. 46 E-mail re Response to Citizen's</p> <p>5 Petition on Talc / Latest Review</p> <p>6 of the Data, Bates JNJ 000426011 452</p> <p>7 No. 47 Draft Minutes Talc Interest Party</p> <p>8 Task Force, April 12, 1994, Bates</p> <p>9 JNJTALC000376526 to 000376528 462</p> <p>10 No. 48 Letter to Mary Wolfe from CTFA,</p> <p>11 Bates IMERYYS 137977 to 137978 468</p> <p>12 No. 49 Federal Register/Vol. 70, No. 200,</p> <p>13 Bates MUSCAT000004007 to 000004013 470</p> <p>14 No. 50 E-mail re Rothman Proposal for</p> <p>15 Updating CTFA Submission of Comments</p> <p>16 to the NTP, Bates JNJ 000391715 to</p> <p>17 000391716 474</p> <p>18 No. 51 Article entitled "Use of cosmetic</p> <p>19 talc on contraceptive diaphragms and</p> <p>20 risk of ovarian cancer: A meta-</p> <p>21 analysis of nine observational</p> <p>22 studies," Bates JNJ 000375876 to</p> <p>23 000375883 479</p> <p>24</p> <p>25</p>
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2	(Attached to transcript)	2	(Attached to transcript)
3	LORETZ DEPOSITION EXHIBITS PAGE	3	LORETZ DEPOSITION EXHIBITS PAGE
4	No. 59 E-mail re IARC Dr. Huncharek	4	No. 71 Code of Federal Regulations,
5	comment, Bates JNJTALC000109051 to	5	Title 21, Chapter 1, Subchapter G,
6	000109060 577	6	Part 740 672
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9	Bailey, Bates BCAL-BAILEY-00000518 592	9	Patient Information (NCI)" 678
10	No. 61 Article entitled "A Meta-Analytical	10	No. 73 E-mail string re missed Kelly phone
11	Approach Examining the Potential	11	call, Bates MBS-CRE000271 to 000272 682
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13	and Ovarian Cancer," Bates JNJ	13	Prevention (PDQ): Prevention -
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20	No. 64 Draft letter never sent (in	20	No. 80 Minutes, Ad Hoc Talc Task Force,
21	handwriting,) Bates JNJ 000024880 620	21	Bates JNJ 000089586 713
22		22	No. 81 Memorandum re Publication of Meta
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4	No. 65 Article entitled "Perineal	4	No. 82 Letter to Stephen Gettings from
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6	of Invasive Epithelial Ovarian Cancer	6	00028675 731
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<p>1 PROCEEDINGS</p> <p>2 -----</p> <p>3 THE VIDEOGRAPHER: The time is 9:09 a.m.</p> <p>4 on October 1st, 2018. This is video 1, Volume II,</p> <p>5 in the continued deposition of Dr. Linda Loretz.</p> <p>6 A reminder to the witness, she is still</p> <p>7 under oath.</p> <p>8 CROSS-EXAMINATION</p> <p>9 BY MR. TISI:</p> <p>10 Q Good morning, Dr. Loretz.</p> <p>11 A Good morning.</p> <p>12 Q Just to remind the jury, what is --</p> <p>13 please state your name, please.</p> <p>14 A Linda Loretz.</p> <p>15 Q Okay. And you are a toxicologist?</p> <p>16 A Yes.</p> <p>17 Q Okay. And you're here represented by</p> <p>18 counsel?</p> <p>19 A Yes.</p> <p>20 Q My name is Chris Tisi. I represent</p> <p>21 women with ovarian cancer who claim that talcum</p> <p>22 powder products like Johnson & Johnson baby powder</p> <p>23 and Shower to Shower powder caused or contributed</p> <p>24 to their ovarian cancer.</p> <p>25 Do you understand that?</p>	<p>1 A Yes.</p> <p>2 Q Okay. And a 30(b)(6) deposition, just</p> <p>3 to get rid of all the legalese there, is a</p> <p>4 deposition where the company puts forward a</p> <p>5 witness to testify on behalf of the company.</p> <p>6 You understand that?</p> <p>7 A Yes.</p> <p>8 Q And you understand that your testimony</p> <p>9 is binding on the company?</p> <p>10 A Yes.</p> <p>11 Q Okay. And you're speaking not only as</p> <p>12 Dr. Loretz, but you're speaking on behalf of the</p> <p>13 Personal Care Products Council?</p> <p>14 A Yes.</p> <p>15 Q And by the Personal Care Products</p> <p>16 Council, you understand that we also mean an</p> <p>17 organization called CTFA?</p> <p>18 A Correct.</p> <p>19 Q Okay. And that's the predecessor name</p> <p>20 for the Personal Care Products Council, and I</p> <p>21 guess it was the Cosmetic Toiletry and</p> <p>22 Fragrance --</p> <p>23 A Association.</p> <p>24 Q -- Association, correct?</p> <p>25 A Correct.</p>
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<p>1 A Yes.</p> <p>2 Q Okay. And by the terms "talcum powder</p> <p>3 products," you understand that I mean cosmetic</p> <p>4 talc used in those products?</p> <p>5 A Yes.</p> <p>6 Q Okay. And if I had a bottle of either</p> <p>7 Shower to Shower here or Johnson's Baby Powder,</p> <p>8 what I'm referring to is everything that's in the</p> <p>9 bottle.</p> <p>10 Do you understand that?</p> <p>11 A Okay, yes.</p> <p>12 Q That includes fragrance, it includes</p> <p>13 whatever is mined from the -- from the mine,</p> <p>14 whatever is in that bottle.</p> <p>15 Do you understand?</p> <p>16 A Okay.</p> <p>17 Q I'm not talking about pure crystalline</p> <p>18 talc.</p> <p>19 A Okay.</p> <p>20 Q Okay? Unless I say otherwise.</p> <p>21 Have we ever met before?</p> <p>22 A I don't believe so.</p> <p>23 Q Okay. You know this is a continuation</p> <p>24 of a 30(b)(6) deposition that we -- we propounded</p> <p>25 on the Personal Care Products Council?</p>	<p>1 Q Yeah. And you understand your testimony</p> <p>2 is also binding on them as well?</p> <p>3 A Yes.</p> <p>4 Q Okay. You also understand that you are</p> <p>5 under oath, and your testimony -- testimony may be</p> <p>6 played for the court or jury to consider amongst</p> <p>7 all the other evidence in the case?</p> <p>8 A I do.</p> <p>9 Q Okay. I'm going to hand you what I</p> <p>10 would like to have marked as -- well, that has</p> <p>11 been marked as Exhibit 1 to your prior deposition.</p> <p>12 We don't have those exhibits here, but I do have a</p> <p>13 copy of it. I don't have a copy for all counsel.</p> <p>14 You are here pursuant to that Second</p> <p>15 Amended Notice of Deposition?</p> <p>16 A Okay, yes.</p> <p>17 Q Okay. All right.</p> <p>18 I'd like to talk to you a bit about what</p> <p>19 was done to prepare for this portion of your</p> <p>20 deposition. Your deposition -- this is a</p> <p>21 continuation of a deposition that happened I</p> <p>22 believe in July.</p> <p>23 A Yes.</p> <p>24 Q Okay. Between July and now, have you</p> <p>25 interviewed or spoken to any other people -- let's</p>

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<p>1 put your counsel aside for a moment -- any other 2 either employees, current or former employees, of 3 Personal Care Products Council? 4 A No, just counsel. Just my counsel 5 and -- 6 Q Have you spoken to any third-party 7 witnesses in this case, people -- for example, 8 employees of Johnson & Johnson, employees of -- of 9 Imerys, outside researchers? 10 A Not about this case, no. 11 Q Okay. What additional work have you 12 done to prepare yourself or further prepare 13 yourself to testify to the topics contained in 14 that notice of deposition? 15 A I met with my attorney for several days 16 reviewing records, minutes, e-mails, documents 17 related. 18 Q Have you spoken to John Bailey at all? 19 A No. 20 Q Have you spoken to John Bailey at all 21 since -- you know who John Bailey is? 22 A Yes. 23 Q Have you spoken to John Bailey at all 24 since -- at any time in this process, including 25 before your first deposition?</p>	<p>1 not prepared to testify to today as -- fully? 2 A Categories, I would say no. 3 Q Okay. Now, I'm going to ask you some 4 questions today relating to specific categories, 5 and I'll list them. 6 1(e), which is dissemination of medical 7 and scientific information on talcum powder and 8 ovarian cancer, 1(f), 1(g), 4(a), 4(c), and 9 categories 8 through 22. 10 I'm just doing that for the record, but 11 broadly they fall into two broad categories, and 12 I'm going to separate my questions to you into two 13 broad categories. Okay? 14 A Okay. 15 Q And the broad categories are this: 16 Communications with the Food and Drug 17 Administration about talcum power products and 18 ovarian cancer, including, for example, the 19 Citizen's Petition issue. 20 A Okay. 21 Q Okay? 22 A Yes. 23 Q The one area that I will not cover that 24 will be covered by one of my colleagues is the CIR 25 report.</p>
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<p>1 A No. 2 Q Have you spoken to any lawyers not your 3 own? 4 A The PCPC lawyers, Tom Myers and Emily 5 Manoso, but beyond that, no. 6 Q Okay. Have you reviewed the notice of 7 deposition that I placed before you, Exhibit 8 No. 1, to refamiliarize yourself with the topics 9 we're here to discuss today? 10 A I've reviewed it before. I haven't 11 reviewed it very, very recently, but -- 12 Q Okay. Is there any topic or topics in 13 that notice for which you have been designated 14 that you do not feel comfortable testifying to 15 today? In other words, that you are not -- your 16 investigation is not complete and you don't have 17 information about the topics. 18 A I mean, I guess I would just note that 19 obviously I wasn't here in the '80s, so I can only 20 go by the records that I have seen. But beyond 21 that, no. 22 Q I guess what I'm asking you, and this is 23 a process that is a little bit of a give and take 24 between you and me, and I -- I just want to ask 25 you, are there any categories there that you're</p>	<p>1 A Okay. 2 Q So you won't hear CIR from me. 3 But other than that, the communications 4 with the FDA will be issues I'll be asking you 5 about. 6 A Okay. 7 Q The second part of it is -- will be 8 about consultants and studies, people with whom 9 you consulted and studies that were performed or 10 not performed at the direction of or with the 11 cooperation with PCPC. 12 A Okay. 13 Q Okay. So just broadly speaking, the two 14 categories are communications with FDA except for 15 CIR, and consultants and -- and studies. 16 A Okay. 17 Q Okay? 18 A Yes. 19 Q All right. So let's get started. 20 I want to talk about first 21 communications with the FDA, and I'd like to use 22 as kind of a fulcrum of our discussions the 23 Citizen's Petition, and you know what I mean by 24 the "Citizen's Petition"? 25 A Yes.</p>

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<p>1 Q Okay. To help us really understand</p> <p>2 this, I prepared a timeline --</p> <p>3 MR. LOCKE: Counsel, can I just ask, I</p> <p>4 mean there were a number of Citizen's Petitions.</p> <p>5 Can you --</p> <p>6 MR. TISI: I'm going to be clear.</p> <p>7 MR. LOCKE: Okay.</p> <p>8 MR. TISI: I'm giving a timeline here,</p> <p>9 and we'll --</p> <p>10 MR. LOCKE: Okay.</p> <p>11 MR. TISI: -- we'll do that.</p> <p>12 BY MR. TISI:</p> <p>13 Q So to begin, I'm going to start with the</p> <p>14 most recent Citizen's Petition, the one that was</p> <p>15 filed in 2008.</p> <p>16 A Yes, mm-hmm.</p> <p>17 Q And you're familiar with that, correct?</p> <p>18 A Yes.</p> <p>19 Q And to help us understand the context in</p> <p>20 which that Citizen's Petition was filed and what</p> <p>21 it is, and we haven't explained it to the jury yet</p> <p>22 and we will, I've prepared a little bit of a</p> <p>23 timeline here. And we're going to kind of mark</p> <p>24 some things so that everybody understands the</p> <p>25 historical context in which that petition was</p>	<p>1 A 2006, no?</p> <p>2 Q 2006. Excuse me.</p> <p>3 A Yes.</p> <p>4 Q Yeah. And the Cancer Coalition</p> <p>5 Prevention citizens filed with the FDA, and that's</p> <p>6 in 2008.</p> <p>7 A Yes.</p> <p>8 Q Okay. And there were other things.</p> <p>9 Those are already on the chart. You agree with</p> <p>10 those?</p> <p>11 A Yes.</p> <p>12 Q Okay. Let's talk for a moment what your</p> <p>13 understanding -- first of all, in the course of</p> <p>14 your work with the PCPC, have you had occasions to</p> <p>15 deal with Citizen's Petitions before, or is this</p> <p>16 the only time that this happened?</p> <p>17 A Before this, this was probably the first</p> <p>18 one. I mean we -- we filed a Citizen's Petitions</p> <p>19 ourselves that came after this. Nothing to do</p> <p>20 with talc.</p> <p>21 Q Right. And so you're familiar with the</p> <p>22 process?</p> <p>23 A Yes.</p> <p>24 Q Okay. So would you tell the members of</p> <p>25 the jury a little bit about what a Citizen's</p>
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<p>1 actually filed.</p> <p>2 And I'm going to give a copy to counsel,</p> <p>3 and we're going to hopefully fill this out</p> <p>4 together, and you correct me if I'm wrong on</p> <p>5 any -- on anything I write on here.</p> <p>6 And we're going to mark this as Exhibit</p> <p>7 No. 41.</p> <p>8 (Exhibit No. 41 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. TISI:</p> <p>11 Q And we may come back to this during the</p> <p>12 course -- back and forth to this during the</p> <p>13 deposition, so I'm going to ask you to kind of --</p> <p>14 we'll kind of put it aside and bring it back and</p> <p>15 all that.</p> <p>16 And just for the members of the jury,</p> <p>17 we've marked on here, we started with 1994, and</p> <p>18 there's a reason why I've done that, which will</p> <p>19 become apparent, and then there's the National</p> <p>20 Toxicology Program 10th Report on Carcinogens</p> <p>21 that's in the year 2000.</p> <p>22 You know what I'm talking about?</p> <p>23 A Yes.</p> <p>24 Q Okay. The IARC review which was 2005.</p> <p>25 Correct?</p>	<p>1 Petition is to the best of your understanding.</p> <p>2 A It's -- it's --</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: It's going to be a very</p> <p>5 simple thing, because I -- I --</p> <p>6 BY MR. TISI:</p> <p>7 Q Simple is -- simple is always better.</p> <p>8 A -- I have a lot of details. I mean</p> <p>9 it's -- it's -- someone can petition FDA to</p> <p>10 request something through a process. I believe</p> <p>11 the process is probably spelled out in the Code of</p> <p>12 Federal Regulations. They can request something</p> <p>13 to FDA, and then FDA has, I believe, an obligation</p> <p>14 to respond within a certain amount of time,</p> <p>15 although they can -- they can respond by saying</p> <p>16 we've gotten it and we're reviewing it, and then</p> <p>17 they need to eventually respond to it.</p> <p>18 Q And are there opportunities for other</p> <p>19 interested parties to file comments to that</p> <p>20 petition?</p> <p>21 A Yes.</p> <p>22 Q Okay. And PCPC has on occasion actually</p> <p>23 filed Citizen's Petitions themselves.</p> <p>24 A Yes.</p> <p>25 Q And we're aware that the -- a Citizen's</p>

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<p style="text-align: right;">Page 404</p> <p>1 Petition was filed by a group called the Cancer 2 Prevention Coalition seeking a cancer warning on 3 cosmetic talc products in 2008. Correct? 4 A Yes. 5 Q Okay. And that was actually filed -- 6 that was actually filed in May of 2008? 7 A I don't remember. 8 Q Okay. Let's see if I can help you here. 9 (Exhibit No. 42 was marked for 10 identification.) 11 BY MR. TISI: 12 Q I'm going to hand you what I've had 13 marked as Exhibit No. 42. 14 Do you recognize this? 15 A Yes. 16 Q Okay. Is this the Citizen's -- is this 17 a Citizen's Petition that was filed on behalf of 18 the Cancer Prevention Coalition with the Food and 19 Drug Administration in -- on May 13th, 2008? 20 A That's what it looks to be, yes. 21 Q Okay. And you're familiar with that 22 document? 23 A Yes. 24 Q And -- 25 MR. TISI: Can we bring this document</p>	<p style="text-align: right;">Page 406</p> <p>1 University of Illinois at Chicago School of Public 2 Health. 3 A Correct. That's what it says. 4 Q And he filed a petition, and it's 5 actually at the very top, it says: "A petition 6 seeking a cancer warning on cosmetic talc 7 products." Do you see that? 8 A Yes. 9 Q Okay. And is this -- and I think you 10 had indicated that nobody from Personal Care 11 Products Council had ever contacted Dr. Epstein to 12 talk to him about the basis for his petition. 13 A Not that I'm aware. 14 Q Okay. And in this document, he was -- 15 and you're familiar with this document, right? 16 A Yes. 17 Q Okay. And Dr. Epstein, if I could 18 summarize, was writing about the potential link 19 between ovarian cancer and -- talcum powder 20 products and ovarian cancer, correct? 21 A Right. 22 Q And this issue was not a new issue, was 23 it? 24 A No. 25 Q Okay. The issue of the connection</p>
<p style="text-align: right;">Page 405</p> <p>1 up. 2 BY MR. TISI: 3 Q The document in front of you, it was 4 filed by a Dr. Epstein. Do you know that? 5 A Yes. 6 Q Has anyone with PCPC ever sought to meet 7 with Dr. Epstein, if you know? 8 A Not that I'm aware. 9 Q And he was a professor of occupational 10 and environmental medicine at the University of 11 Illinois Chicago Medical Center. That's in the 12 first paragraph. 13 MR. LOCKE: Objection. 14 THE VIDEOGRAPHER: Counsel, can we go 15 off the record? 16 The time is 9:23 a.m. We're going off 17 the record. 18 (Technical difficulties.) 19 THE VIDEOGRAPHER: The time is 9:27 20 a.m., and we're back on the record. 21 BY MR. TISI: 22 Q Just to reask the question, if you look 23 at the first paragraph, this Dr. Epstein 24 identifies himself as the professor emeritus of 25 occupational and environmental medicine,</p>	<p style="text-align: right;">Page 407</p> <p>1 between talcum powder products and ovarian cancer 2 was one that went back into the 1970s, correct? 3 A I think the '80s. I thought it was the 4 first paper published in 1982 that I'm aware of. 5 Q Okay. Then that's what -- we'll use 6 that. 7 And if we can go back to our timeline, 8 if I wrote on top of here that -- concerns that -- 9 MR. TISI: Off the record? 10 (A discussion was held off the record.) 11 MR. TISI: We do need to see that. 12 THE VIDEOGRAPHER: The time is 9:30 a.m. 13 We're going off the record. 14 (Pause in the proceedings.) 15 THE VIDEOGRAPHER: The time is 9:31 a.m. 16 We're back on the record. 17 BY MR. TISI: 18 Q And, Dr. Loretz, I'm sorry for the 19 technical difficulties we're having here. I took 20 the break to write down what I think we agreed. 21 Beginning in about 1982, concerns were 22 raised that talcum powder products may cause or 23 contribute to ovarian cancer; is that correct? 24 A That's correct. 25 Q Okay. And starting in 1982, that issue</p>

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<p>1 was an issue that was one that wasn't just one 2 that was raised and forgotten, it was an issue 3 that was persistently discussed in the medical and 4 scientific literature from that point forward. 5 Fair? 6 A Yes. 7 Q Okay. So it was discussed in the '80s, 8 '90s, 2000s, and in fact, it's still being 9 discussed today. 10 A Yes. 11 Q And by 2008, which would have been about 12 20 -- two decades plus since those initial 13 reports, the Cancer Prevention Coalition filed a 14 petition to the FDA that asked the FDA to mandate, 15 require, that all talcum powder products have some 16 kind of warning for ovarian cancer. True? 17 A That's what the petition says, yes. 18 Q Okay. And so if you go to page 2 of the 19 letter. 20 MR. TISI: Can you please go back? 21 BY MR. TISI: 22 Q Section A, it says: "Agency action 23 requested," and point number 1, it says: 24 "Immediately require cosmetic talcum powder 25 products to bear labels with a prominent warning</p>	<p>1 Q Okay. So taking off your hat of 2 Dr. Loretz and putting on your hat as Personal 3 Care Products Council, can you tell us when the 4 Personal Care Products Council first became aware 5 of this petition? 6 A I'm sure it was soon after it was filed. 7 Q So it was filed in May of 2008. It 8 would have been approximately May of 2008. 9 A Yes. I believe so. 10 Q All right. Let's put that aside for a 11 moment. We'll come back to that. 12 Now, in July of 2009, did the Personal 13 Care Products Council file a white paper with the 14 FDA or comments with the FDA opposing the Cancer 15 prevention -- Prevention Coalition petition? 16 A Yes. 17 Q And that was filed on July 21st, 2009. 18 Correct? 19 A I don't recall. 20 Q Let me see if I can provide you with 21 what I have marked as Exhibit No. 43. 22 (Exhibit No. 43 was marked for 23 identification.) 24 BY MR. TISI: 25 Q Is that the PCPC -- I'm sorry.</p>
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<p>1 such as 'Frequent talc application in the female 2 genital area is responsible for major risks of 3 ovarian cancer.' 4 Do you see that? 5 A Yes. 6 Q Did I read that correctly? 7 A That's what it says. 8 Q Okay. And Dr. Epstein also asked to be 9 heard by the FDA on this petition, correct? 10 A That's what it says, yes. 11 Q Okay. So not only did he file a letter 12 requesting that the -- a warning be added to 13 talcum powder products, but he also wanted to meet 14 with them, correct? 15 A That's what it says, yes. 16 Q All right. You became -- the Personal 17 Care Products Council became aware of this 18 petition -- do you remember when it became aware 19 of this petition? 20 A I really don't. 21 Q Okay. Do you remember the circumstances 22 under which it became aware of this petition? 23 A I don't remember the details, no. I'm 24 sure it was -- I'm sure it was soon after it was 25 filed, but I don't remember the details.</p>	<p>1 Is this the response of the Personal 2 Care Products Council to the Epstein petition to 3 add a warning? 4 A Yes. 5 Q Okay. Now, is it fair to say, and if 6 you go to the -- the position of the Personal Care 7 Products Council is the addition of a warning 8 label on products such as Johnson & Johnson's baby 9 powder and Shower to Shower would be inappropriate 10 and unnecessary? 11 A You're reading that somewhere? 12 Q It's the very last -- second to last 13 paragraph at the end. 14 A Yes. 15 Q And so just to make sure that we're kind 16 of 2000 -- at 30,000 feet, the petition was filed 17 asking for a warning. The petition of the 18 Personal Care Products Council was no warning was 19 necessary. 20 A That's correct. 21 Q In this petition did the Personal Care 22 Products Council lay out the standard for when a 23 warning is appropriate, if you know? 24 A I believe our response to the petition 25 was to look at the science on talcum powder and</p>

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<p>1 ovarian cancer.</p> <p>2 Q Okay. But the question that I asked is</p> <p>3 a different one.</p> <p>4 The standard of when a warning is</p> <p>5 required is a standard that you're familiar with?</p> <p>6 A That sounds more like a legal concept,</p> <p>7 so I'm not sure that I am.</p> <p>8 Q Well, does the Personal Care Products</p> <p>9 Council provide a labeling manual for its members?</p> <p>10 A We do, but it's -- it's -- yes, it's a</p> <p>11 summary of existing labeling requirements,</p> <p>12 regulatory requirements.</p> <p>13 Q Right. Does this petition --</p> <p>14 Dr. Epstein asked for a label to be added,</p> <p>15 correct?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q And this opposes the addition of a</p> <p>20 label, correct?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. TISI:</p> <p>24 Q Did the Personal Care Products Council</p> <p>25 in any way analyze or -- or discuss the standard</p>	<p>1 Loretz. You're speaking here as a -- as the</p> <p>2 organization.</p> <p>3 A Okay.</p> <p>4 Q And the organization is responding to a</p> <p>5 request to add a warning. Right?</p> <p>6 A Yes.</p> <p>7 Q And the -- presumably -- I mean, maybe I</p> <p>8 should ask you the question: Did PCPC consult</p> <p>9 with the requirements for adding a warning before</p> <p>10 responding to this petition?</p> <p>11 MR. LOCKE: Objection.</p> <p>12 THE WITNESS: I -- I mean, we don't</p> <p>13 agree with the petitioner's rationale for adding a</p> <p>14 warning.</p> <p>15 BY MR. TISI:</p> <p>16 Q I understand you -- you have a</p> <p>17 difference in the weight of the evidence that</p> <p>18 would support or not support a warning.</p> <p>19 My question is, did you understand at</p> <p>20 the time the standard for what -- what would</p> <p>21 require a warning or not?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: I think it was our</p> <p>24 understanding this would not require a warning.</p> <p>25 BY MR. TISI:</p>
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<p>1 for providing when a label -- to add a warning on</p> <p>2 a cosmetic product is required?</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: We -- as I say, what we</p> <p>5 did was we reviewed the science on ovarian cancer,</p> <p>6 talcum powder, and our position is that there is</p> <p>7 not evidence of a causative role, and therefore we</p> <p>8 did not believe a -- a label is necessary.</p> <p>9 MR. TISI: Okay. Move to strike.</p> <p>10 BY MR. TISI:</p> <p>11 Q My question was a different one.</p> <p>12 Does this opposition that was filed in</p> <p>13 July of 2009 contain any discussion of what the</p> <p>14 standard is?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: No, it addresses the</p> <p>17 science.</p> <p>18 BY MR. TISI:</p> <p>19 Q Okay. Do you know whether or not the</p> <p>20 standard requires that causation be proven before</p> <p>21 a warning be added?</p> <p>22 A I -- I think that sounds like a legal</p> <p>23 question. I -- I --</p> <p>24 Q I'm asking you since this was filed</p> <p>25 on -- you're -- you're speaking here not as Linda</p>	<p>1 Q Well, what was the standard?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: I'm not sure I understand</p> <p>4 that question.</p> <p>5 BY MR. TISI:</p> <p>6 Q Okay. Did the standard require that --</p> <p>7 and if you don't know the answer, you don't know</p> <p>8 the answer, okay?</p> <p>9 But does the standard for providing a</p> <p>10 warning require that causation be proven, be</p> <p>11 unequivocal?</p> <p>12 MR. LOCKE: Objection. That's beyond</p> <p>13 the scope.</p> <p>14 You can answer in your personal</p> <p>15 capacity.</p> <p>16 THE WITNESS: I'm not sure what you mean</p> <p>17 by the standard for requiring a warning.</p> <p>18 BY MR. TISI:</p> <p>19 Q Well, this is -- this is a response to a</p> <p>20 request that a warning be added.</p> <p>21 A Correct. Which FDA later said it</p> <p>22 doesn't require a warning.</p> <p>23 Q That's not --</p> <p>24 MR. TISI: Move to strike.</p> <p>25 BY MR. TISI:</p>

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<p>1 Q Okay. My -- my -- my question is, did 2 the PCPC consult what the legal -- what the legal 3 standard was for when a warning is required? 4 MR. LOCKE: Objection. 5 THE WITNESS: I mean, I -- I -- I think 6 it's fair to say we have a lot of lawyers at PCPC, 7 and if they felt this were inappropriate from a 8 legal standpoint to have this position, we would 9 not have that position. 10 BY MR. TISI: 11 Q Did they set out what the standard is in 12 the letter? Is there anything in this letter -- 13 first of all, who drafted this cover letter? 14 A It was either myself or John Bailey. 15 Q Okay. Did you consult with -- either 16 one of you consult with what the standard is for 17 when a warning is required before writing this 18 letter? 19 MR. LOCKE: Objection. 20 THE WITNESS: I'm -- again, I'm not 21 quite sure when what you mean "when a warning was 22 required." By whom? 23 BY MR. TISI: 24 Q Well, you -- you know -- do you know 25 that warnings are added when a cosmetic product</p>	<p>1 level of evidence that's required before a label 2 is added? 3 MR. LOCKE: Objection. Beyond the 4 scope. 5 BY MR. TISI: 6 Q If you don't know, you don't know. 7 A Yeah, I -- I guess I would say I don't 8 know, but I -- 9 Q That's fine. But you wrote this letter 10 anyway, you or Dr. Bailey wrote this letter to the 11 FDA responding to requests for requiring a label. 12 A Again, I would say certainly there was 13 awareness within PCPC, and it was felt that this 14 was appropriate as a response. 15 Q Right. And there was -- but there was 16 no discussion about what the standard is under the 17 Code of Federal Regulations in this -- in this 18 letter, correct? 19 MR. LOCKE: Objection. 20 THE WITNESS: And again, I would just 21 say our -- our view was that -- that there was not 22 a need for warning because of the lack of 23 evidence. 24 BY MR. TISI: 25 Q Okay. Well, as -- as we discussed</p>
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<p>1 may cause -- there's evidence that they may cause 2 a potential harm? 3 MR. LOCKE: Objection. Beyond the 4 scope. 5 You can answer in your personal 6 capacity. 7 THE WITNESS: I'm sorry. What's the 8 question? 9 BY MR. TISI: 10 Q Do you know that warnings can be added 11 voluntarily when there's evidence that the product 12 may cause a potential harm? 13 MR. LOCKE: Same objection, and to form. 14 THE WITNESS: And as our position being 15 that there was not support for that harm, we would 16 not have supported adding a voluntary label. 17 BY MR. TISI: 18 Q I -- I understand. 19 A We would not have said, yes, this should 20 be labeled. 21 Q But should -- do you not understand what 22 the standard is for a label? 23 MR. LOCKE: Objection. 24 BY MR. TISI: 25 Q What is -- what is the -- what is the</p>	<p>1 before, this issue was one that was debated in the 2 medical and scientific community for almost 25 3 years before this petition was filed, correct? 4 A It was a topic, yes. 5 Q All right. And some epidemiologists 6 looking at the evidence felt that there -- there 7 was sufficient evidence to raise a causal 8 inference, correct? 9 MR. LOCKE: Objection. 10 BY MR. TISI: 11 Q Including Dr. Epstein. 12 MR. LOCKE: Objection. 13 THE WITNESS: Dr. Epstein did, but I 14 think the literature, as we point out and as we 15 had our epidemiologists point out, that there is a 16 lot of inconsistency. 17 BY MR. TISI: 18 Q Understood. My -- I understand that's 19 your position. 20 My question, though, is a different one, 21 Dr. Loretz. There were epidemiologists and -- and 22 scientists in the medical and scientific 23 communication who disagreed with the PCPC's view 24 of the sufficiency of the evidence. This was an 25 active debate, correct?</p>

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<p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: That's probably fair to</p> <p>3 say, and certainly Dr. Epstein disagreed.</p> <p>4 BY MR. TISI:</p> <p>5 Q Right. And there were others. I mean</p> <p>6 Dr. Cramer, another -- another doctor who you are</p> <p>7 familiar with, wrote and published -- and</p> <p>8 published in the literature several -- several of</p> <p>9 the studies. You know that he felt and published</p> <p>10 that there was an inference of causation, true?</p> <p>11 MR. LOCKE: Objection.</p> <p>12 THE WITNESS: I believe that would be</p> <p>13 true, and then the -- there were epidemiologists</p> <p>14 who did not agree with that.</p> <p>15 BY MR. TISI:</p> <p>16 Q Fine. Okay. And that kind of</p> <p>17 illustrates a point that I think is important to</p> <p>18 make here.</p> <p>19 Looking at the evidence that -- some of</p> <p>20 which was summarized in this letter, reasonable --</p> <p>21 scientists looking at the evidence could reach</p> <p>22 different conclusions looking at that evidence,</p> <p>23 and in fact, did reach different conclusions,</p> <p>24 correct?</p> <p>25 MR. LOCKE: Objection.</p>	<p>1 Citizen's Petition," and that would be July 2009.</p> <p>2 Okay?</p> <p>3 A Yes.</p> <p>4 MR. LOCKE: I'm just going to object. I</p> <p>5 mean it says "Comments" on it. It doesn't say</p> <p>6 "opposition to," but --</p> <p>7 BY MR. TISI:</p> <p>8 Q But I think -- I think the testimony was</p> <p>9 this was in opposition to adding a warning,</p> <p>10 correct?</p> <p>11 A Yes. We did not think a warning was</p> <p>12 necessary.</p> <p>13 Q Okay. So let's put that aside for a</p> <p>14 moment.</p> <p>15 Oh, I'm sorry, before -- before we leave</p> <p>16 this document, if you go to page 4 of 39 of this</p> <p>17 document, you attach a report.</p> <p>18 A Yes.</p> <p>19 Q PCPC attaches a report. And this is a</p> <p>20 report by a group called the Meta-Analysis</p> <p>21 Research Group. Correct?</p> <p>22 A Yes.</p> <p>23 Q Okay. And that's a group that you're</p> <p>24 familiar with?</p> <p>25 A Yes.</p>
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<p>1 THE WITNESS: Yeah, there were different</p> <p>2 opinions.</p> <p>3 BY MR. TISI:</p> <p>4 Q Okay. And there were different opinions</p> <p>5 based upon the evidence, correct?</p> <p>6 A I don't want to go to what the -- what</p> <p>7 the thoughts were, but I mean, there's a body of</p> <p>8 scientific literature, yes.</p> <p>9 Q Right. And that's not unusual. You've</p> <p>10 been in this business for -- for a while.</p> <p>11 Scientists and doctors look at -- look at the</p> <p>12 evidence, and some -- they can often disagree</p> <p>13 about evidence, correct?</p> <p>14 A That's true.</p> <p>15 Q All right. All right. So let's put</p> <p>16 this opposition to the Citizen's Petition on our</p> <p>17 timeline here, and this was --</p> <p>18 MR. TISI: Maybe we can switch back to</p> <p>19 this.</p> <p>20 THE VIDEOGRAPHER: It is. It's in</p> <p>21 process.</p> <p>22 MR. TISI: If I can see if I can write</p> <p>23 it.</p> <p>24 BY MR. TISI:</p> <p>25 Q This would be "PCPC opposition to</p>	<p>1 Q Okay. And it was prepared by a</p> <p>2 Dr. Michael Huncharek?</p> <p>3 A Yes.</p> <p>4 Q And a Dr. Joshua Muscat?</p> <p>5 A Correct.</p> <p>6 Q And they both identify themselves as</p> <p>7 being with the Meta-Analysis Research Group.</p> <p>8 A As well as other affiliations, but yes.</p> <p>9 Q All right. And we'll get into this in a</p> <p>10 minute, but this report was initially written for</p> <p>11 Johnson & Johnson, correct?</p> <p>12 A Yes.</p> <p>13 Q And it was then -- in fact, earlier</p> <p>14 versions of this have "Prepared for Johnson &</p> <p>15 Johnson." This version that was submitted to the</p> <p>16 FDA says "Prepared for the Personal Care Products</p> <p>17 Council." Correct?</p> <p>18 A That could be, yes.</p> <p>19 Q Okay. And it was actually prepared for</p> <p>20 Johnson & Johnson, but --</p> <p>21 A Originally.</p> <p>22 Q Originally. It was not prepared for or</p> <p>23 initiated by the Personal Care Products Council,</p> <p>24 correct?</p> <p>25 A We took it over, though, yes.</p>

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<p style="text-align: right;">Page 424</p> <p>1 Q Right.</p> <p>2 A I mean, and submitted it, yes.</p> <p>3 Q All right. But J&J did not submit the</p> <p>4 report. The Personal Care Products Council did.</p> <p>5 A Correct.</p> <p>6 Q Now, I think in your prior deposition</p> <p>7 you said you had met Dr. Huncharek and Dr. Muscat</p> <p>8 before, correct?</p> <p>9 A I'm not sure if I ever met</p> <p>10 Dr. Huncharek. I know I met Dr. Muscat once upon</p> <p>11 a time.</p> <p>12 Q Okay. Had you had occasion to</p> <p>13 communicate with them either on teleconferences or</p> <p>14 by e-mail?</p> <p>15 A I had spoken to Dr. Huncharek.</p> <p>16 Q Okay. How often?</p> <p>17 A Once or twice.</p> <p>18 Q Okay. Now, on page 6 of this document</p> <p>19 is an introduction. Do you see that?</p> <p>20 A Yes.</p> <p>21 Q It identifies -- the second paragraph</p> <p>22 identifies this report as "an independent review</p> <p>23 of the relevant data." Do you see that?</p> <p>24 A Sorry, where?</p> <p>25 Q Second -- second paragraph, second to</p>	<p style="text-align: right;">Page 426</p> <p>1 conclusions at all. That's a --</p> <p>2 Q Right. And in fact, these -- these</p> <p>3 doctors, Meta-Analysis Research Group, had been</p> <p>4 consultants to the talc industry before this,</p> <p>5 correct?</p> <p>6 A They had --</p> <p>7 MR. LOCKE: Objection.</p> <p>8 BY MR. TISI:</p> <p>9 Q I'm sorry. You may answer the question.</p> <p>10 A They had, yes. Or Dr. Muscat had</p> <p>11 reviewed for NTP.</p> <p>12 Q Okay. And you were aware through</p> <p>13 Crowell & Moring that they were both retained to</p> <p>14 provide information on NTP for the 12 -- 12th</p> <p>15 review on carcinogens, correct?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: I'm not sure if --</p> <p>18 BY MR. TISI:</p> <p>19 Q You ever heard of Crowell & Moring?</p> <p>20 A I've heard of them, yes.</p> <p>21 Q Okay. Do you know -- did you</p> <p>22 communicate with them through Crowell & Moring?</p> <p>23 A Communicate with?</p> <p>24 Q Huncharek and Muscat.</p> <p>25 A Oh, no. No.</p>
<p style="text-align: right;">Page 425</p> <p>1 last sentence.</p> <p>2 A Okay.</p> <p>3 Q It identifies this as "an independent</p> <p>4 review of the relevant data."</p> <p>5 A Okay.</p> <p>6 Q Do you see that?</p> <p>7 A Yes.</p> <p>8 Q Okay. This was not an independent</p> <p>9 review of the relevant data, was it?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: I think it depends how you</p> <p>12 define "independent." I mean these -- the</p> <p>13 epidemiologists that were retained -- I mean,</p> <p>14 first of all, this was on behalf of our members,</p> <p>15 not just J&J. They initiated the contact and got</p> <p>16 the report writing started.</p> <p>17 I think independent in the sense that</p> <p>18 these were the conclusions of these</p> <p>19 epidemiologists.</p> <p>20 BY MR. TISI:</p> <p>21 Q Right. But this report was written with</p> <p>22 Johnson & Johnson and Imerys's input, correct?</p> <p>23 A We probably had all of our members who</p> <p>24 were interested are allowed -- you know, would</p> <p>25 review it, but that doesn't mean we change the</p>	<p style="text-align: right;">Page 427</p> <p>1 Q Did you -- and you know that they</p> <p>2 appeared as an industry representative for --</p> <p>3 Dr. Muscat appeared at the IARC proceedings as an</p> <p>4 industry member?</p> <p>5 A I do know that.</p> <p>6 MR. LOCKE: Well, wait -- wait one</p> <p>7 second. When you say "they appeared," who are you</p> <p>8 referring to?</p> <p>9 MR. TISI: I said Dr. Muscat.</p> <p>10 MR. LOCKE: Okay.</p> <p>11 BY MR. TISI:</p> <p>12 Q Are you aware of that?</p> <p>13 A I'm aware of that, yes.</p> <p>14 Q You know who Robert Glenn is, don't you?</p> <p>15 A I know who he is.</p> <p>16 Q Okay. You know he is with Crowell &</p> <p>17 Moring?</p> <p>18 A Yes.</p> <p>19 Q And you received e-mails from him,</p> <p>20 correct?</p> <p>21 A Well, not in relation to this.</p> <p>22 Q Well, with relation to Huncharek and</p> <p>23 Muscat, correct?</p> <p>24 A Only -- the only -- the only thing I</p> <p>25 believe I received e-mails from him, just as a --</p>

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<p>1 being copied was related to the IARC review.</p> <p>2 Q Okay. And you also understand -- we'll</p> <p>3 talk about this in a moment -- they let you know</p> <p>4 that there were publications that were being</p> <p>5 planned by Huncharek and Muscat, true?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: I'm not sure. I may have</p> <p>8 known.</p> <p>9 BY MR. TISI:</p> <p>10 Q Okay. We'll talk about those. We'll</p> <p>11 talk about those.</p> <p>12 But -- but the bigger picture, Doctor,</p> <p>13 is that Huncharek and Muscat were people who had</p> <p>14 been in communication with the talc industry going</p> <p>15 back to at least 2000 and perhaps before.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: Muscat in 2000, I'm</p> <p>18 certainly aware of that.</p> <p>19 BY MR. TISI:</p> <p>20 Q And you said you had spoken to Huncharek</p> <p>21 as well.</p> <p>22 A I spoke to him I believe around the time</p> <p>23 of this, I think. I spoke to him once, I know</p> <p>24 that, and I can't remember exactly when it was.</p> <p>25 Q Okay. Now, prior to the talc -- prior</p>	<p>1 what Dr. Huncharek did.</p> <p>2 Q Okay. Do you know whether or not they</p> <p>3 were an organization that was a contract research</p> <p>4 organization? For example, do you know whether or</p> <p>5 not they were litigation consultants? Do you know</p> <p>6 whether or not they were -- you know, what they</p> <p>7 were?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: I mean I think we were</p> <p>10 familiar with them from doing this. This to me --</p> <p>11 so we know they did this kind of meta-analysis,</p> <p>12 which again was something I know that both</p> <p>13 Dr. Huncharek and Dr. Muscat did. So...</p> <p>14 MR. TISI: I'm going to -- I'm going to</p> <p>15 actually move to strike.</p> <p>16 BY MR. TISI:</p> <p>17 Q My question was, do you know -- or did</p> <p>18 you do any due diligence as to what Meta-Analysis</p> <p>19 Research Group was?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: No, because we knew who</p> <p>22 the authors were.</p> <p>23 (Exhibit No. 44 was marked for</p> <p>24 identification.)</p> <p>25 BY MR. TISI:</p>
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<p>1 to this publication, had you ever heard of the</p> <p>2 Meta-Analysis Research Group ever?</p> <p>3 MR. LOCKE: When you refer to "this</p> <p>4 publication," you mean Exhibit 43?</p> <p>5 MR. TISI: Correct.</p> <p>6 BY MR. TISI:</p> <p>7 Q Let me -- let me rephrase the question,</p> <p>8 because -- to be clear.</p> <p>9 Prior to these comments that were</p> <p>10 submitted to the FDA in July of 2009 under the</p> <p>11 letterhead of Meta-Analysis Research Group, had</p> <p>12 you ever had occasion to come across Meta-Analysis</p> <p>13 Research Group before then?</p> <p>14 A I honestly don't know. I believe</p> <p>15 Dr. Muscat's affiliation was not that in 2000.</p> <p>16 Q It was American Health Foundation.</p> <p>17 A That's what I remember as well.</p> <p>18 Q Okay. So my question is, did you --</p> <p>19 prior to submitting this independent report on</p> <p>20 behalf of the industry by a group called</p> <p>21 Meta-Analysis Research Group, did PCPC do any due</p> <p>22 diligence as to who Meta-Analysis Research Group</p> <p>23 is and what their focus was?</p> <p>24 A I -- I think the assumption was that</p> <p>25 they were doing meta-analysis, which I know is</p>	<p>1 Q Okay. I'm going to show you Exhibit</p> <p>2 No. 44.</p> <p>3 And I'm not concerned with the front</p> <p>4 pages of it. But with an attachment.</p> <p>5 Here you go.</p> <p>6 MR. TISI: I'm sorry? Oh, Tom, I'm</p> <p>7 sorry, here you go.</p> <p>8 MR. LOCKE: Thank you.</p> <p>9 MR. TISI: Yep.</p> <p>10 BY MR. TISI:</p> <p>11 Q And if you go to the last -- and I'll</p> <p>12 just represent to you, this is a proposal from</p> <p>13 Dr. Huncharek to Bob Glenn to do certain papers</p> <p>14 and research on behalf of Imerys in 2004.</p> <p>15 But attached to it --</p> <p>16 MR. LOCKE: Let's let the witness just</p> <p>17 read it first a second, just flip through the</p> <p>18 pages.</p> <p>19 MR. TISI: Oh, she can certainly do</p> <p>20 that, Tom.</p> <p>21 BY MR. TISI:</p> <p>22 Q And I'm going to ask you on the -- about</p> <p>23 the brochure that's attached on page 5.</p> <p>24 A (Peruses document.)</p> <p>25 Q Since you took the time to read it, let</p>

14 (Pages 428 to 431)

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<p>1 me just ask you the question. Do you see that</p> <p>2 this is a proposal to write two papers, one on</p> <p>3 meta-analysis on diaphragms and one a critical</p> <p>4 review of the talc literature?</p> <p>5 A Yes.</p> <p>6 Q Okay. You know that they did publish</p> <p>7 two articles relating to that very specific --</p> <p>8 those two specific topics, correct?</p> <p>9 A I believe so, yes.</p> <p>10 Q Okay. And so this is a proposal by --</p> <p>11 by Dr. Huncharek to write such articles to</p> <p>12 Mr. Glenn, who I will represent to you was with</p> <p>13 the lawyers for Crowell & Moring for Imerys.</p> <p>14 A Okay.</p> <p>15 Q Okay. Attached to that is a brochure</p> <p>16 from the Meta-Analysis Research Group. Do you see</p> <p>17 that?</p> <p>18 A I guess this is --</p> <p>19 MR. LOCKE: Page 5.</p> <p>20 THE WITNESS: Okay. Okay.</p> <p>21 BY MR. TISI:</p> <p>22 Q Okay. This is a brochure. Did you</p> <p>23 ever -- I think I -- I asked you before, but did</p> <p>24 you ever ask -- first of all, the report that was</p> <p>25 filed on behalf of the FDA, I believe your answers</p>	<p>1 litigation?</p> <p>2 A I'm not sure. I knew that Dr. Muscat</p> <p>3 was deposed, but I don't -- I don't think that's</p> <p>4 the same as what you're asking.</p> <p>5 Q And so my question to you is, did it</p> <p>6 matter to you when you were submitting this on</p> <p>7 behalf of -- to the FDA as to whether or not these</p> <p>8 consultants who -- were basically people who would</p> <p>9 be involved in litigation?</p> <p>10 MR. LOCKE: Objection. Do you mean --</p> <p>11 BY MR. TISI:</p> <p>12 Q Did you think about that?</p> <p>13 MR. LOCKE: Do you mean -- when you say</p> <p>14 "this," you're referring to Exhibit 43, the</p> <p>15 comments?</p> <p>16 MR. TISI: Correct, in 2009.</p> <p>17 BY MR. TISI:</p> <p>18 Q Did you want to know -- did you even</p> <p>19 think to know whether or not these witnesses,</p> <p>20 Dr. Huncharek and Dr. Muscat, would be considered</p> <p>21 or groomed for being experts in litigation?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: That's not --</p> <p>24 MR. LOCKE: Objection. Did you mean to</p> <p>25 say "these witnesses"?</p>
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<p>1 to interrogatories said it cost about \$50,000.</p> <p>2 A I think that's correct, yeah.</p> <p>3 Q Okay. Did PCPC pay that or did J&J?</p> <p>4 A I believe we did.</p> <p>5 Q Okay. "We" meaning PCPC?</p> <p>6 A I'm sorry. PCPC.</p> <p>7 Q On behalf of the talc industry?</p> <p>8 A Yes.</p> <p>9 Q And one of the things that the</p> <p>10 Meta-Analysis Research Group identifies in the</p> <p>11 first paragraph that they do is they assist major</p> <p>12 pharmaceutical companies and other clients in,</p> <p>13 quote, deciphering often complex, seemingly</p> <p>14 contradictory, data using rigorous meta-analysis</p> <p>15 methods.</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q Do you see on the next page that it also</p> <p>19 provides medical and legal consulting in</p> <p>20 litigation?</p> <p>21 A That's what it says, yes.</p> <p>22 Q The expert witnesses. Do you see that?</p> <p>23 A Yes.</p> <p>24 Q Do you know that both Dr. Huncharek and</p> <p>25 Dr. Muscat became expert witnesses in talc</p>	<p>1 MR. TISI: These -- yes, these doctors.</p> <p>2 THE WITNESS: We hired them for their</p> <p>3 epidemiological expertise, and they're -- they</p> <p>4 were not always favorable to us. I mean they</p> <p>5 also -- Dr. Huncharek published on hair dyes, and</p> <p>6 it was -- it was not favorable. So we -- we</p> <p>7 consider them to be fair, and their scientist</p> <p>8 arguments would stand.</p> <p>9 BY MR. TISI:</p> <p>10 Q Okay. Had you ever heard discussed --</p> <p>11 now I'm asking you as Linda Loretz -- had you ever</p> <p>12 discussed that if this case went into litigation</p> <p>13 that Drs. Huncharek and Muscat would be</p> <p>14 consultants or experts?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. TISI:</p> <p>18 Q Okay. Do you know that Meta-Analysis</p> <p>19 Research Group went out of business shortly after</p> <p>20 this --</p> <p>21 A I don't know. I did not know that.</p> <p>22 Q Do you know that they became paid</p> <p>23 litigation experts in 2010?</p> <p>24 A No.</p> <p>25 Q Now, are you aware that in 2011, after</p>

15 (Pages 432 to 435)

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<p>1 the filing of this report to PCPC, that they took</p> <p>2 their analysis that was paid for by PCPC and then</p> <p>3 made some modifications, but for the most part,</p> <p>4 published it as it was in the -- in the</p> <p>5 literature?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: I'm -- I think I'm aware</p> <p>8 that there was a publication, but, no, I did not</p> <p>9 know that was happening until after the fact -- we</p> <p>10 did not know that that was happening until after</p> <p>11 the fact.</p> <p>12 (Exhibit No. 45 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. TISI:</p> <p>15 Q I'm going to show you what I've had</p> <p>16 marked as Exhibit No. 45.</p> <p>17 And this is a --</p> <p>18 (Phone interruption.)</p> <p>19 BY MR. TISI:</p> <p>20 Q This is an article that I will represent</p> <p>21 to you is very close to, if not identical in many</p> <p>22 paragraphs, to the report that was filed on behalf</p> <p>23 of PCPC. Have you seen this before?</p> <p>24 A I've -- yes.</p> <p>25 Q It was published in 2011. Correct?</p>	<p>1 talking about before.</p> <p>2 And it's on page 3 of the report,</p> <p>3 page 6 -- 6 of 9 of the letter. Do you see that?</p> <p>4 A Yes.</p> <p>5 Q Okay. The Introduction says: "On</p> <p>6 May 13th, 2008, Samuel Epstein, MD, chairman of</p> <p>7 the Cancer Prevention Coalition, submitted a</p> <p>8 Citizen's Petition to the Commissioner of the Food</p> <p>9 and Drug Administration seeking placement of a</p> <p>10 cancer warning label on talc products. The</p> <p>11 petition requests the Commissioner of the Food and</p> <p>12 Drug require that all talcum powders bear labels</p> <p>13 with warnings such as 'Frequent application of</p> <p>14 talcum powder in the female genital area</p> <p>15 substantially increases the risk of ovarian</p> <p>16 cancer.'"</p> <p>17 Did I read that correctly?</p> <p>18 A That's what it says.</p> <p>19 Q Okay. The second paragraph -- so that</p> <p>20 just -- and that's true, that that's -- that</p> <p>21 paragraph is true, that's what Epstein did.</p> <p>22 A I would say yes.</p> <p>23 Q Okay. Second paragraph is -- is your</p> <p>24 response or the summary of your response.</p> <p>25 "Given the multiple implications of such</p>
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<p>1 A Accepted April 2011, so -- yes.</p> <p>2 Q Do you know -- do you know that there</p> <p>3 was a -- actually a proposal to -- made to Imerys</p> <p>4 that -- to turn this paper, "this" meaning the</p> <p>5 report that was submitted by PCPC in July of 2009,</p> <p>6 into a publication?</p> <p>7 A No. We were not involved.</p> <p>8 Q Okay. If you look at the back of the</p> <p>9 article, do you know -- does it acknowledge PCPC</p> <p>10 as having paid for this report?</p> <p>11 A No.</p> <p>12 Q Is there anything in that acknowledgment</p> <p>13 that would indicate that at the time that this</p> <p>14 article was published that they were paid</p> <p>15 litigation experts for the lawyers representing</p> <p>16 Johnson & Johnson?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: No, not any</p> <p>19 acknowledgments.</p> <p>20 BY MR. TISI:</p> <p>21 Q So let's put this on our timeline here,</p> <p>22 2011. And I'll put "H&M publication, 2011."</p> <p>23 Now, let's go back to the report that</p> <p>24 was filed with the FDA. And I would like to go</p> <p>25 back to the Introduction section that we started</p>	<p>1 warning labels, the Personal Care Products Council</p> <p>2 sought an evaluation of the validity of the</p> <p>3 scientific facts underlying this request. The</p> <p>4 Meta-Analysis Research Group was retained to</p> <p>5 provide an independent review of the relevant</p> <p>6 data. Below are the findings of that review."</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q I'm curious about the statement saying</p> <p>10 "the multiple implications of such warning</p> <p>11 labels." Do you see that?</p> <p>12 A Yes.</p> <p>13 Q Can you tell us on behalf of the PCPC</p> <p>14 what the multiple implications of the warning</p> <p>15 labels are that you were referring to?</p> <p>16 MR. LOCKE: Objection. Obviously this</p> <p>17 was written by doctors --</p> <p>18 MR. TISI: I'm -- I'm -- I am --</p> <p>19 BY MR. TISI:</p> <p>20 Q What are the multiple implications that</p> <p>21 were being considered there?</p> <p>22 A Again, this -- this was written not by</p> <p>23 us. I mean, I think it's pretty obvious that that</p> <p>24 would have -- could have an impact -- I mean,</p> <p>25 again, we didn't think a label was -- should be</p>

16 (Pages 436 to 439)

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<p>1 required because we -- because of the science</p> <p>2 behind it we believe was not supported, but</p> <p>3 obviously would have an impact on -- on the</p> <p>4 product if -- if it were.</p> <p>5 Q Okay. The "impact on the product," what</p> <p>6 do you mean?</p> <p>7 A Well, we -- we -- I mean it --</p> <p>8 Q Well, let me ask --</p> <p>9 A We don't think it should have a warning</p> <p>10 if it's -- if we don't believe that it --</p> <p>11 Q Let me ask you some -- I didn't mean to</p> <p>12 interrupt you. Go finish, if you'd like.</p> <p>13 A No, just that if -- because we didn't --</p> <p>14 we don't believe that the science shows causation,</p> <p>15 we just did not believe you have a warning to</p> <p>16 scare people off of something if it's not real.</p> <p>17 Q Okay. So let me ask you -- I understand</p> <p>18 your position that you did not think the evidence</p> <p>19 supported a causal inference.</p> <p>20 Putting that issue aside, the company</p> <p>21 through its consultants assert -- make an</p> <p>22 assertion that warnings labels would have</p> <p>23 implications. Do you see that?</p> <p>24 A Yes.</p> <p>25 Q And not only implications, have multiple</p>	<p>1 than stating what Dr. Epstein did, the first --</p> <p>2 first sentence of that paragraph, you say that</p> <p>3 the -- that your consultants on your behalf say:</p> <p>4 "Given the multiple implications on such a warning</p> <p>5 label, the Personal Care Products Council sought</p> <p>6 an evaluation of the validity of the scientific</p> <p>7 facts underlying this request."</p> <p>8 So this statement is the predicate of</p> <p>9 why the PCPC got this report in the first place,</p> <p>10 correct?</p> <p>11 A Sure.</p> <p>12 Q Okay. And so the predicate was that</p> <p>13 there were multiple implications of that warning,</p> <p>14 of a warning, should it be required. And this, to</p> <p>15 be clear, is a request that warning labels be</p> <p>16 mandated. Correct?</p> <p>17 A Correct.</p> <p>18 Q And you were aware that companies can</p> <p>19 and in fact have voluntarily added a warning,</p> <p>20 correct?</p> <p>21 A Sure.</p> <p>22 Q Okay. So this is different than that.</p> <p>23 I mean companies can voluntarily add a warning.</p> <p>24 A Yes.</p> <p>25 Q But this is in the absence of a company</p>
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<p>1 implications. Correct?</p> <p>2 A That's what it says.</p> <p>3 Q Okay. And I'm curious as to what those</p> <p>4 implications were from your perspective, from the</p> <p>5 PCPC's perspective.</p> <p>6 Was there concern ever expressed that</p> <p>7 adding a warning would have an impact on the</p> <p>8 members of the PCPC? You've heard that, correct?</p> <p>9 A Yeah, again --</p> <p>10 Q Okay.</p> <p>11 A -- I think the reason that -- we would</p> <p>12 not want that, though, is because we do believe</p> <p>13 the science doesn't support the need for a</p> <p>14 warning.</p> <p>15 Q I -- I understand.</p> <p>16 A It has to be part of the context of my</p> <p>17 answer.</p> <p>18 Q I'm going -- Doctor, I'm going to ask</p> <p>19 you a lot about this document, okay? And we're</p> <p>20 going to go through it probably more than you want</p> <p>21 to. Okay?</p> <p>22 A Sure.</p> <p>23 Q But before we do, I want to understand</p> <p>24 the context in which it's written. Okay?</p> <p>25 And in the very first paragraph, other</p>	<p>1 voluntarily adding a warning, they're going right</p> <p>2 to the FDA and saying, The companies are not doing</p> <p>3 it, and we're going to ask you -- require you to</p> <p>4 do it. Correct?</p> <p>5 A Yes.</p> <p>6 Q All right. And the PCPC, as a predicate</p> <p>7 for opposing that requirement, laid out that there</p> <p>8 are multiple implications to requiring that</p> <p>9 warning. Correct?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: That's what it says, yes.</p> <p>12 BY MR. TISI:</p> <p>13 Q All right. And the multiple -- the</p> <p>14 implications are -- I mean let's -- let's -- I'm</p> <p>15 going to lay out some for you and ask you whether</p> <p>16 they were things that were discussed at the time.</p> <p>17 Was one of the implications that it</p> <p>18 would affect the commercial interests of the</p> <p>19 members of the PCPC?</p> <p>20 A With the context being that we did not</p> <p>21 believe that it truly had this risk, you do not</p> <p>22 want to affect sales and so forth without --</p> <p>23 Q Okay.</p> <p>24 A -- if it's -- if there's no reason for</p> <p>25 having a warning.</p>

17 (Pages 440 to 443)

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<p>1 Q Understood. We're going to talk about 2 the reasons. 3 A Okay. 4 Q I just want to know the implications. 5 A Okay. 6 Q Right? 7 A Yep. 8 Q So the first implication would be -- and 9 I will write it on here, "Implications of 10 warnings. 1. Sales." 11 Had you ever heard in the context -- 12 since there were multiple implications, had you 13 ever heard in the context that providing a warning 14 after this being in the medical literature for 25 15 years would open up members to the potential -- 16 for the reason why we're all here today, potential 17 lawsuits? 18 A No. 19 Q You never heard that? 20 MR. LOCKE: Objection. 21 THE WITNESS: We never talked about 22 that. 23 BY MR. TISI: 24 Q Never talked about that at all? 25 A No.</p>	<p>1 A Yes. 2 Q All right. And so what I'm trying to 3 explore with you is what potential -- and I'll put 4 it right on the table -- what potential biases 5 might have been present when this opposition was 6 sent to the FDA. Okay? 7 A Okay. 8 Q All right. So we'll talk about the 9 science and we'll talk -- but before we talk about 10 the science, I want to talk about the prism 11 through which you looked at the science. Okay? 12 A Okay. 13 Q And one of the things that was a concern 14 to the members, we talked about sales. Had you 15 ever heard of any concerns about litigation? 16 A I can tell you that was not something we 17 ever discussed. 18 Q Okay. Is it something you understood? 19 A Sure. At some level, of course. 20 Q Okay. And if sales -- people stop 21 selling talc, and use corn starch, for example, 22 instead of talc, that may impact the membership of 23 the PCPC as well, correct? 24 MR. LOCKE: Objection. 25 THE WITNESS: I mean I didn't -- no,</p>
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<p>1 Q You never heard that -- that adding a 2 warning might -- might raise -- might cause people 3 to bring claims such as this? 4 A We just talked about the science. 5 Q I'm not -- I'm going to talk about the 6 science in a moment, okay? We're going to get to 7 the science. 8 But oftentimes -- you're aware as a 9 scientist that oftentimes the reason why we do 10 disclosures in medical and scientific literature 11 is so that people could understand the biases or 12 potential biases or potential conflicts of 13 interest that the authors might have, correct? 14 MR. LOCKE: Objection. 15 THE WITNESS: Say it one more time. 16 BY MR. TISI: 17 Q Medical articles oftentimes come with 18 disclosures about affiliations, conflicts of 19 interest. 20 A Sure. 21 Q And the reason why we do that -- 22 A Yes. 23 Q -- is so that people reading those 24 articles can understand why -- perhaps biases that 25 the authors bring to the table, correct?</p>	<p>1 that's not -- that's not what I thought. I mean 2 to me that -- that wouldn't really make sense. I 3 mean if you have a product that's corn starch 4 instead of talc, it's still a product. So I don't 5 think that's really relevant. 6 BY MR. TISI: 7 Q Right. But Imerys -- Imerys doesn't 8 manufacture corn starch, do they? 9 A No, but I -- I guess -- 10 Q So they would fall out of the -- they 11 might fall out of the PCPC, correct? 12 A I don't -- no, I never thought about, 13 and I don't think -- I never ever heard anybody 14 mention that. 15 Q Any of the -- any other -- since there 16 were multiple implications, any other implications 17 you could think of as to why you sought to get 18 this independent evaluation to submit to the FDA 19 in opposition to letting women know there was a 20 potential for ovarian cancer based upon the 21 literature? 22 A I think given -- 23 MR. LOCKE: Objection. 24 THE WITNESS: -- given our position that 25 we don't believe there is a causal role, I don't</p>

18 (Pages 444 to 447)

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<p>1 think you want to put warnings on products</p> <p>2 suggesting that there's some harm when there's</p> <p>3 not, scaring people or having people think that</p> <p>4 some harm that they've experienced has something</p> <p>5 to do with this when in fact it doesn't.</p> <p>6 BY MR. TISI:</p> <p>7 Q So you were concerned about scaring</p> <p>8 people. With baby powder.</p> <p>9 A Yeah, a warning is --</p> <p>10 Q Okay.</p> <p>11 A -- is a scary thing, sure.</p> <p>12 Q And if -- if a woman was told that --</p> <p>13 that talcum powder products, and we talked about</p> <p>14 this for 25 years that was being discussed in the</p> <p>15 medical literature, if they were concerned by</p> <p>16 that, there were other alternatives on -- on the</p> <p>17 shelves, right? There was corn starch, correct?</p> <p>18 MR. LOCKE: Objection.</p> <p>19 THE WITNESS: Yeah, again, the context</p> <p>20 to me is that if we did not believe that it was a</p> <p>21 real risk, that's where you don't want to warn.</p> <p>22 BY MR. TISI:</p> <p>23 Q And -- well, but that's my reason why I</p> <p>24 asked you before what the standard was. If the</p> <p>25 standard was -- is the standard for warning that</p>	<p>1 literature on ovarian cancer?</p> <p>2 A No.</p> <p>3 Q Okay. Since 2009, did PCPC ever discuss</p> <p>4 with its members whether or not its members should</p> <p>5 voluntarily add an informational label or warning</p> <p>6 label about perineal dusting with talcum powder</p> <p>7 products?</p> <p>8 A No.</p> <p>9 Q Do you know that some talcum powder</p> <p>10 products have in fact voluntarily added warnings</p> <p>11 or information about the potential risk of talcum</p> <p>12 powder products?</p> <p>13 A I didn't know that, but --</p> <p>14 Q Are you familiar with a company called</p> <p>15 Belk -- Belcam Inc.?</p> <p>16 A No.</p> <p>17 Q Greenbriar?</p> <p>18 A No.</p> <p>19 Q Assured?</p> <p>20 A No.</p> <p>21 Q Okay. There are members -- there are</p> <p>22 people who actually manufacture talcum powder</p> <p>23 products that are not members of the PCPC,</p> <p>24 correct?</p> <p>25 A I would assume so.</p>
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<p>1 you have to be convinced of a real risk?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 BY MR. TISI:</p> <p>4 Q Or that there may be a risk. What is</p> <p>5 the standard for a warning, and did you even know</p> <p>6 at the time you sent this to the FDA?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: Again, I would just say</p> <p>9 there were people within -- within PCPC who know a</p> <p>10 lot more on this topic than I do, and --</p> <p>11 BY MR. TISI:</p> <p>12 Q Did they --</p> <p>13 A -- the awareness of --</p> <p>14 Q Did you send this to the lawyers at the</p> <p>15 PCPC, this letter?</p> <p>16 A This -- I can't recall exactly who read</p> <p>17 it, but I can tell you that certainly, you know,</p> <p>18 everything that -- when things like this happen,</p> <p>19 they are -- it's known without the associate --</p> <p>20 throughout the association at the higher levels.</p> <p>21 Q Now, prior to this time, did the PCPC</p> <p>22 ever discuss either with the FDA or whether or not</p> <p>23 it's members should voluntary add a warning or</p> <p>24 precaution or informational statement about</p> <p>25 cosmetic talc and the current state of the</p>	<p>1 Q Are you aware that some manufacturers</p> <p>2 have stopped selling talcum powder products</p> <p>3 altogether and use -- and just have decided to use</p> <p>4 corn starch, correct? Do you know that?</p> <p>5 MR. LOCKE: Objection.</p> <p>6 THE WITNESS: I guess I don't know that,</p> <p>7 but I could find it plausible.</p> <p>8 BY MR. TISI:</p> <p>9 Q Okay. Let's get back to the response to</p> <p>10 the Citizen's Petition.</p> <p>11 Do you know -- we mentioned before, and</p> <p>12 I just want to make sure that we understand, this</p> <p>13 PCPC response was actually commissioned by</p> <p>14 Johnson & Johnson in 2008, correct?</p> <p>15 A I believe they started the process</p> <p>16 rolling, yes.</p> <p>17 Q Well, it's more than starting the</p> <p>18 process. The report was actually written for J&J.</p> <p>19 A I -- I -- yeah, I think when we got it,</p> <p>20 it was -- it was --</p> <p>21 Q It was pretty --</p> <p>22 A The report had been -- was in pretty</p> <p>23 good shape, yes.</p> <p>24 Q It was -- it was pretty much written by</p> <p>25 the time you got it.</p>

19 (Pages 448 to 451)

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<p>1 A I believe so, yes.</p> <p>2 Q Did you understand this was a</p> <p>3 collaborative response by J&J and Imerys</p> <p>4 primarily?</p> <p>5 A I'm not sure that I did.</p> <p>6 Q Did other manufacturers -- there are</p> <p>7 other manufacturers of talcum powder products,</p> <p>8 correct?</p> <p>9 A There are certainly other people on our</p> <p>10 Talc Task Force or the people with an interest in</p> <p>11 talc.</p> <p>12 Q Do you know --</p> <p>13 A Other companies, rather.</p> <p>14 Q Do you know that -- whether they had</p> <p>15 input into this PCPC response, or was it primarily</p> <p>16 a J&J, with the assistance of Imerys, production?</p> <p>17 A I believe we would have sent it to other</p> <p>18 people with interest. I mean, that's our normal</p> <p>19 process.</p> <p>20 Q Do you know whether that was happening?</p> <p>21 A I mean, I don't, but that would be our</p> <p>22 normal process.</p> <p>23 (Exhibit No. 46 was marked for</p> <p>24 identification.)</p> <p>25 BY MR. TISI:</p>	<p>1 submission, this was submitted by a PCPC employee</p> <p>2 by the name of John Bailey. I want to talk to you</p> <p>3 a little bit about who John Bailey is and was.</p> <p>4 A Okay.</p> <p>5 Q Who is John Bailey?</p> <p>6 A He -- at the time of this, he was the</p> <p>7 vice president of science -- the science</p> <p>8 department. He was my boss -- or, rather, the</p> <p>9 executive vice president of the science department</p> <p>10 at PCPC.</p> <p>11 Q Okay. He previously worked at the FDA,</p> <p>12 didn't he?</p> <p>13 A He did.</p> <p>14 Q And in fact, he was hired directly from</p> <p>15 the FDA by PCPC.</p> <p>16 A That's correct.</p> <p>17 Q Okay. And at the time that he left the</p> <p>18 FDA in December of 2001, he was with what</p> <p>19 division, do you know?</p> <p>20 A Office of Cosmetics and Colors.</p> <p>21 Q And at that time in 2001, the NTP had</p> <p>22 actually deferred consideration of talc as a -- a</p> <p>23 carcinogen, correct?</p> <p>24 A Yes.</p> <p>25 Q Okay. And when we say "deferred," I</p>
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<p>1 Q So I'm going to show you what I've had</p> <p>2 marked as Exhibit No. 46. And it's a date -- and</p> <p>3 you're not on this, but I'm doing this just to</p> <p>4 kind of see if I can hone in the time frame.</p> <p>5 This is an e-mail from Kathleen Wille.</p> <p>6 Do you know who Kathleen Wille is?</p> <p>7 A Yes.</p> <p>8 Q Okay. She works with J&J?</p> <p>9 A Yeah, I'm not sure if she's still there,</p> <p>10 but yes.</p> <p>11 Q And it's entitled "Response to Citizens</p> <p>12 Petition on Talc, Latest Review of the Data," and</p> <p>13 its attachment is a J&J report. Do you see that?</p> <p>14 A Yes.</p> <p>15 Q Okay. And it says: "This is the report</p> <p>16 that we will -- that we will submit to FDA in</p> <p>17 response to the Citizen's Petition. We originally</p> <p>18 commissioned the work; however, the trade</p> <p>19 association will be the submitter."</p> <p>20 Is that an accurate statement of what</p> <p>21 happened?</p> <p>22 A I don't know, but I'm -- well, yes, they</p> <p>23 commissioned it, and we -- we submitted it, that's</p> <p>24 correct, yes.</p> <p>25 Q Okay. Now, going back to the actual FDA</p>	<p>1 want to stop and pause on that for a moment</p> <p>2 because it -- I just want to make absolutely</p> <p>3 clear, and we'll talk about this in a moment.</p> <p>4 They deferred the question, they did not</p> <p>5 decide the question.</p> <p>6 A That's what -- that was under the</p> <p>7 official, what they did, yes.</p> <p>8 Q Okay. And so in that context, PCPC just</p> <p>9 immediately following that -- well, when it was</p> <p>10 deferred, there was an understanding that the</p> <p>11 issue might come up again.</p> <p>12 A Yes.</p> <p>13 Q And in fact, it did come up again,</p> <p>14 correct?</p> <p>15 A Kind of.</p> <p>16 Q It came up with IARC?</p> <p>17 A Oh, it came up in other contexts, sure.</p> <p>18 Q Came up in IARC?</p> <p>19 A Yes.</p> <p>20 Q This issue -- and again, it bears</p> <p>21 repeating because I want to make sure -- at all</p> <p>22 times on this continuum, on this timeline, the</p> <p>23 issue of talcum powder products causing or</p> <p>24 contributing to ovarian cancer was an active</p> <p>25 debate. Sometimes more active, sometimes less</p>

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<p style="text-align: right;">Page 456</p> <p>1 active. But this was something that was a concern</p> <p>2 to your members throughout the entire time of this</p> <p>3 timeline.</p> <p>4 MR. LOCKE: Objection. Form.</p> <p>5 THE WITNESS: It was being talked about</p> <p>6 by someone.</p> <p>7 BY MR. TISI:</p> <p>8 Q Right. And so in the context of hiring</p> <p>9 Dr. Bailey, he was hired by -- by PCPC from the</p> <p>10 division of the FDA, the Office of colors --</p> <p>11 Cosmetics and Colors --</p> <p>12 A Cosmetics and Colors.</p> <p>13 Q -- that would interact with the cosmetic</p> <p>14 industry on talc issues, correct?</p> <p>15 A As well as many other issues, yes.</p> <p>16 Q Right. And the person who took over was</p> <p>17 a Dr. Katz?</p> <p>18 A Yes.</p> <p>19 Q And Dr. Katz worked for Dr. -- had</p> <p>20 worked for Dr. Bailey at the time, correct?</p> <p>21 A I actually don't know that.</p> <p>22 Q All right. And he was the director of</p> <p>23 that office, correct?</p> <p>24 A That's correct, yes.</p> <p>25 Q And when he left FDA in December of</p>	<p style="text-align: right;">Page 458</p> <p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. TISI:</p> <p>4 Q And he was -- he was going to the very</p> <p>5 same office that he ran, correct?</p> <p>6 A In -- at that meeting there was more</p> <p>7 than just the Office of Cosmetics and Colors.</p> <p>8 Q Well, we're going to talk about that.</p> <p>9 But -- but the people who were -- the vast</p> <p>10 majority of the people at that FDA employees were</p> <p>11 people from the Office of Cosmetics and Colors.</p> <p>12 A I'm not sure about the vast majority,</p> <p>13 but certainly there were people there, and that --</p> <p>14 that may well be right.</p> <p>15 Q Including Dr. Katz.</p> <p>16 A Dr. Katz was there.</p> <p>17 Q And I want to put this on a timeline in</p> <p>18 a moment, but Dr. Bailey left PCPC after this</p> <p>19 petition -- this opposition was -- was correct,</p> <p>20 filed?</p> <p>21 A He's -- he left, yes. I'm not sure</p> <p>22 exactly -- the exact year, but yes.</p> <p>23 Q About 2011 -- 2010, 2011?</p> <p>24 A That sounds roughly right.</p> <p>25 Q Okay. So before we discuss the science</p>
<p style="text-align: right;">Page 457</p> <p>1 2001, he became -- he was hired in January of 2002</p> <p>2 by PCPC.</p> <p>3 A I couldn't confirm those dates, but --</p> <p>4 Q Okay. And he interacted with the -- and</p> <p>5 we're going to talk about this -- he's writing the</p> <p>6 response to this petition that would go to the</p> <p>7 very same division, the Office of Cosmetics and</p> <p>8 Colors, that actually he ran while he was at the</p> <p>9 FDA.</p> <p>10 A Yes, although I think the heart of our</p> <p>11 submission is the scientific analysis.</p> <p>12 Q Right.</p> <p>13 A Not the cover letter, but the --</p> <p>14 Q But the cover letter -- the cover</p> <p>15 letter -- well, let's -- let's call it what it is.</p> <p>16 He actually sent the letter and he actually met</p> <p>17 with you -- with you at the Office of Cosmetics</p> <p>18 and Colors before this was filed in July.</p> <p>19 A Oh --</p> <p>20 Q There was a meeting at the FDA --</p> <p>21 A Correct.</p> <p>22 Q -- where you and Dr. Bailey went to the</p> <p>23 FDA, previewed this document that Dr. Huncharek</p> <p>24 and Muscat had provided, and then filed it</p> <p>25 subsequently, correct?</p>	<p style="text-align: right;">Page 459</p> <p>1 that was provided by PCPC, and I told you we would</p> <p>2 do that, let's see if we can pause here and put</p> <p>3 together -- fill out our timeline a little bit</p> <p>4 about the context of everything that happened.</p> <p>5 First of all, we talked about the fact</p> <p>6 that talcum powder products may cause or</p> <p>7 contribute to ovarian cancer was a concern since</p> <p>8 the early 1980s and it was debated throughout the</p> <p>9 entire time, correct?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: There were ongoing</p> <p>12 happenings related to that topic, yes.</p> <p>13 BY MR. TISI:</p> <p>14 Q Okay. Can we say -- can we use the word</p> <p>15 "consistent" here? It was a consistent topic of</p> <p>16 discussion in the medical and scientific</p> <p>17 community?</p> <p>18 A There were a number of publications, but</p> <p>19 I mean not every --</p> <p>20 Q I mean I'm not saying you woke up in the</p> <p>21 morning and discussed it. I'm saying that within</p> <p>22 this topic was a topic that was -- it wasn't just</p> <p>23 a flash in the pan. It was something that was</p> <p>24 discussed over the -- over this 25 years</p> <p>25 represented by this chart.</p>

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<p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: Again, with the</p> <p>3 understanding that there were publications, but</p> <p>4 not all of them showed any sort of association --</p> <p>5 BY MR. TISI:</p> <p>6 Q And some did.</p> <p>7 A -- and some did and some -- and some did</p> <p>8 and some -- but there were a lot of weaknesses in</p> <p>9 the --</p> <p>10 Q Well, I mean, my question is that was an</p> <p>11 active debate, correct, what those studies meant?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: I guess that's fair to</p> <p>14 say.</p> <p>15 BY MR. TISI:</p> <p>16 Q Okay. So can we write "Active debate</p> <p>17 between scientists." Is that okay?</p> <p>18 A Okay.</p> <p>19 MR. LOCKE: Objection.</p> <p>20 BY MR. TISI:</p> <p>21 Q Is that accurate?</p> <p>22 MR. LOCKE: Same objection.</p> <p>23 THE WITNESS: I -- I suppose.</p> <p>24 BY MR. TISI:</p> <p>25 Q Okay. All right. So, for example, some</p>	<p>1 Q I'll show you a document, if I -- if I</p> <p>2 could, but that was an issue that PCPC knew and</p> <p>3 understood that the FDA was concerned about.</p> <p>4 A They --</p> <p>5 MR. LOCKE: Objection.</p> <p>6 THE WITNESS: They had an interest and a</p> <p>7 concern with, okay.</p> <p>8 (Exhibit No. 47 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. TISI:</p> <p>11 Q I'm going to show you a document that</p> <p>12 I've marked as Exhibit No. 47, and it's draft</p> <p>13 minutes of the CTFA talc force.</p> <p>14 And we're going to talk about this</p> <p>15 later, but this is Exhibit No. -- I said 47?</p> <p>16 MR. LOCKE: Yes.</p> <p>17 BY MR. TISI:</p> <p>18 Q Now you see why I used 1994 is on my --</p> <p>19 A Mm-hmm.</p> <p>20 Q -- on my timeline here.</p> <p>21 A Yes, right, but the -- the workshop,</p> <p>22 yes.</p> <p>23 Q Okay. And this was a workshop dated</p> <p>24 April 12th, 1994, correct?</p> <p>25 A Yes.</p>
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<p>1 like Dr. Cramer or Dr. Epstein on one hand thought</p> <p>2 there was -- that there was evidence of a causal</p> <p>3 association, and some people like Huncharek and</p> <p>4 Muscat thought there was not.</p> <p>5 MR. LOCKE: Objection.</p> <p>6 THE WITNESS: There were different</p> <p>7 opinions, yes.</p> <p>8 BY MR. TISI:</p> <p>9 Q Based on the same literature.</p> <p>10 A Yes.</p> <p>11 Q Okay. Now, another point before we put</p> <p>12 things on a timeline, the PCPC knew that the FDA</p> <p>13 had been concerned about the issue since at least</p> <p>14 the 1990s, correct?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: They responded before,</p> <p>17 yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q But they were concerned about the issue.</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: I -- I guess, yes. I</p> <p>22 mean --</p> <p>23 BY MR. TISI:</p> <p>24 Q Well, I mean don't guess.</p> <p>25 A Well --</p>	<p>1 Q Okay. It's actually written by a</p> <p>2 Stephen Gettings?</p> <p>3 A Yes.</p> <p>4 Q Who is Dr. Gettings?</p> <p>5 A Dr. Gettings was my predecessor.</p> <p>6 Q All right. And this is a report of a</p> <p>7 meeting amongst -- this is the Talc Interested</p> <p>8 Party Task Force. Among other things, Johnson &</p> <p>9 Johnson and the predecessor for Luzenac were</p> <p>10 there.</p> <p>11 A Yes.</p> <p>12 Q Okay. And I'm going to come back to</p> <p>13 this in a minute when I talk about the second area</p> <p>14 which we talked about, which is studies.</p> <p>15 A Okay.</p> <p>16 Q But -- but I'm just concerned with point</p> <p>17 number 1. It says: "It was noted that the FDA</p> <p>18 still appears to be concerned with the issue of</p> <p>19 ovarian cancer as evidenced by their contact with</p> <p>20 the NTP."</p> <p>21 Do you see that?</p> <p>22 A Yes.</p> <p>23 Q Okay. So at least as of this date,</p> <p>24 you're aware that the FDA had some concerns about</p> <p>25 talc and ovarian cancer.</p>

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<p>1 A Okay.</p> <p>2 Q Is that accurate?</p> <p>3 A I'm going to say yes.</p> <p>4 Q Okay. So let's put this on our timeline</p> <p>5 here, 1994. And this would be "Task force with</p> <p>6 the FDA, concern about ovarian cancer."</p> <p>7 By the way, ovarian cancer, this is not</p> <p>8 a trivial issue, is it?</p> <p>9 A No.</p> <p>10 Q And ovarian cancer is a -- ovarian</p> <p>11 cancer is -- affects 20 -- 20,000 -- 20,000 women</p> <p>12 a year get diagnosed with ovarian cancer, correct?</p> <p>13 A Yes.</p> <p>14 Q It has a high mortality rate. Correct?</p> <p>15 A Yes. Yes.</p> <p>16 Q Very serious.</p> <p>17 A Absolutely.</p> <p>18 Q And by contrast, baby powder is not a</p> <p>19 necessary pharmaceutical, correct?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 BY MR. TISI:</p> <p>22 Q Is it fair to say you can live without</p> <p>23 baby powder?</p> <p>24 MR. LOCKE: Objection. Beyond the</p> <p>25 scope.</p>	<p>1 was talking before, people can look at the same</p> <p>2 evidence and come to different conclusions,</p> <p>3 correct?</p> <p>4 A I think there was some different</p> <p>5 evidence. I think it really was bringing forth</p> <p>6 some things that were mistaken in the draft</p> <p>7 report, particularly regarding mineralogy and --</p> <p>8 and so forth.</p> <p>9 Q Right. And one of the things -- one of</p> <p>10 the things that was the basis of the deference is</p> <p>11 that there was not a clear understanding of what</p> <p>12 at that time was in talcum powder products.</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I think there wasn't</p> <p>15 also -- there was not a clear definition of -- in</p> <p>16 fact, when they wanted to look at it again or</p> <p>17 considered looking at it again, they changed the</p> <p>18 name of what they were going to look at, because</p> <p>19 it was hard -- it was not clear what they were</p> <p>20 trying to look at, and that was something that got</p> <p>21 discussion at the NTP, and I think that made a</p> <p>22 difference and explains part of why there were</p> <p>23 different conclusions from the first two review</p> <p>24 groups.</p> <p>25 BY MR. TISI:</p>
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<p>1 BY MR. TISI:</p> <p>2 Q Talcum powder.</p> <p>3 A Yes.</p> <p>4 Q Now, in 2000, we have the NTP 10th</p> <p>5 Report on Carcinogen, and we talk about the word</p> <p>6 "defer."</p> <p>7 And I want to write that clearly because</p> <p>8 my handwriting is terrible.</p> <p>9 Okay. And they deferred the question.</p> <p>10 A They did. They did vote. They voted,</p> <p>11 but then they deferred.</p> <p>12 Q Right.</p> <p>13 A But they voted against listing seven to</p> <p>14 three, but then they deferred.</p> <p>15 Q Well, there were different -- okay.</p> <p>16 Since you raised that, let's -- you knew this was</p> <p>17 going to happen. I was not going to get into it,</p> <p>18 but let's -- let's -- there were three committees</p> <p>19 that looked at the -- looked at this, correct?</p> <p>20 A Mm-hmm.</p> <p>21 Q Two of them voted in favor of listing.</p> <p>22 A That's correct.</p> <p>23 Q And one voted against, correct?</p> <p>24 A Yes.</p> <p>25 Q Okay. And that's kind of the issue I</p>	<p>1 Q All right. And the third review group</p> <p>2 was not unanimous, was it?</p> <p>3 A They -- they did do a vote. I -- I've</p> <p>4 been calling it seven to three against listing,</p> <p>5 and then they -- and then they decided to defer</p> <p>6 because there were --</p> <p>7 Q And again, that's -- that's -- that's</p> <p>8 the kind of example that I'm talking about of even</p> <p>9 if it was seven to three against listing talc,</p> <p>10 there were three people who thought that it should</p> <p>11 be listed, correct?</p> <p>12 A Sure.</p> <p>13 Q So this is -- this is kind of</p> <p>14 crystalizing what we've been talking about, which</p> <p>15 is different scientists can look at the evidence</p> <p>16 and reach different conclusions, true?</p> <p>17 A Yes.</p> <p>18 Q And in fact, did reach different</p> <p>19 conclusions, correct?</p> <p>20 A Yes.</p> <p>21 Q All right. Okay. So we put that on our</p> <p>22 timeline here.</p> <p>23 Now, prior to that last discussion --</p> <p>24 prior to that deferral, that last meeting, the</p> <p>25 PCPC actually drafted or commissioned a report,</p>

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<p>1 correct?</p> <p>2 A You mean -- to be submitted to the</p> <p>3 NTP --</p> <p>4 Q Yes.</p> <p>5 A -- for the meeting? Yes.</p> <p>6 Q Yeah. And I'm just going to identify</p> <p>7 it because I don't want to go into it, but -- but</p> <p>8 here is a copy of the actual letter, Exhibit</p> <p>9 No. 48.</p> <p>10 (Exhibit No. 48 was marked for</p> <p>11 identification.)</p> <p>12 BY MR. TISI:</p> <p>13 Q And one of the things that the -- and</p> <p>14 this would have been -- we'll put it on our</p> <p>15 timeline, this would have been December of 2000</p> <p>16 and -- 2000. So we will put "PCPC CFTA</p> <p>17 submission."</p> <p>18 And the only reason I bring this up is</p> <p>19 Dr. Muscat is the very same doctor who --</p> <p>20 Dr. Muscat wrote a report that was submitted to</p> <p>21 NTP, correct?</p> <p>22 A That's correct.</p> <p>23 Q All right. And it's the very same</p> <p>24 Dr. Muscat that wrote the report with -- which was</p> <p>25 a Citizen's Petition with Dr. Huncharek.</p>	<p>1 that at the actual meeting, but I -- that's what I</p> <p>2 recall. I think we walked away knowing where they</p> <p>3 came out, but I -- I could be wrong on that, but,</p> <p>4 yes, it was confirmed then. Certainly.</p> <p>5 (Exhibit No. 49 was marked for</p> <p>6 identification.)</p> <p>7 BY MR. TISI:</p> <p>8 Q Okay. And I'm going to hand you Exhibit</p> <p>9 No. 40 -- 49. And this is the Code of Federal</p> <p>10 Regulations dated 2005. But if you look at the</p> <p>11 back, the last page with a 12 Bates stamp at the</p> <p>12 end.</p> <p>13 A Okay.</p> <p>14 Q And it says the basis was the NTP</p> <p>15 deferred -- do you see that "Basis for</p> <p>16 nomination"?</p> <p>17 A Yes.</p> <p>18 Q It says: "The NTP deferred</p> <p>19 consideration of listing talc asbestiform and</p> <p>20 non-asbestiform talc in the 10th RoC because its</p> <p>21 2000 review of talc found that there's been</p> <p>22 considerable confusion over the mineral nature and</p> <p>23 consequences of talc, both containing asbestiform</p> <p>24 fibers and not containing asbestiform fibers."</p> <p>25 Do you see that?</p>
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<p>1 A It is.</p> <p>2 Q Okay. So we're going to put "Muscat"</p> <p>3 there. Okay.</p> <p>4 Now, Dr. Muscat was actually recommended</p> <p>5 to the PCPC by Johnson & Johnson, correct? Back</p> <p>6 in 2000.</p> <p>7 A I think that's correct.</p> <p>8 Q So I don't have to use a document. Is</p> <p>9 that correct? I'm happy to use the document,</p> <p>10 but --</p> <p>11 A Okay. Then I'm going to say I think --</p> <p>12 yes, I believe that's correct.</p> <p>13 Q Okay. We just cut ourselves five</p> <p>14 minutes, so --</p> <p>15 A Yea.</p> <p>16 Q All right. And just to kind of put it</p> <p>17 again on our timeline, when did the -- when did</p> <p>18 the NTP defer the issue of whether or not talc was</p> <p>19 a carcinogen?</p> <p>20 A I believe they actually did it at their</p> <p>21 actual meeting, which was in December of 2000.</p> <p>22 Q 2000. And -- you became aware of the</p> <p>23 actual deferral in the CFR? The Code of Federal</p> <p>24 Regulations actually lists it as being --</p> <p>25 A Yeah, I mean I -- I thought they said</p>	<p>1 A Yes.</p> <p>2 Q It further says: "It became evident</p> <p>3 that the literature on both forms of talc with few</p> <p>4 exceptions provide inadequate characterization of</p> <p>5 the adequate material under study," and you see --</p> <p>6 and it just continues from there.</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q Okay. And so the question at that point</p> <p>10 was deferred because there was a question as to</p> <p>11 what was cosmetic talc.</p> <p>12 A Well, I mean this is where it was</p> <p>13 withdrawn.</p> <p>14 Q No, withdrawn --</p> <p>15 A This is 2005.</p> <p>16 Q 2005. But in the basis for -- it talks</p> <p>17 about what happened in the --</p> <p>18 A Oh, the deferral that they're referring</p> <p>19 to, yes, correct.</p> <p>20 Q Okay. All right. And then in 12, in</p> <p>21 the -- it was renominated in 2004, correct?</p> <p>22 A Right.</p> <p>23 Q Right. And so I'm going to put year</p> <p>24 "2004," I'm going to put "renominated NTP." NTP.</p> <p>25 My handwriting is terrible.</p>

24 (Pages 468 to 471)

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<p>1 And -- but at that time it -- the IARC 2 had also taken up the issue, correct? 3 A I'm not sure when I learned about IARC 4 taking up the issue, but I think they -- I mean, 5 so I'm not sure. 6 Q Okay. And IARC is what? 7 A International Agency for Research on 8 Cancer. 9 Q Is it a reputable organization? 10 A It's an arm of the World Health 11 Organization. 12 Q Is it one that in your view is one that 13 is -- does good science? 14 A They have -- I mean, it's -- 15 Q You may disagree with them on occasion, 16 but do they do good science? 17 A It's a closed process, and I think 18 they're considered reputable. It is a very closed 19 process. 20 Q When you say "closed," they don't have 21 people from industry who come in and -- and 22 participate, correct? 23 A Well -- 24 Q People affiliated with industry cannot 25 sit on the panels, correct? There are limitations</p>	<p>1 possible, correct? To be. 2 A Yes. 3 Q Now, in 2005, you know that Dr. Muscat 4 and Huncharek were retained by Imerys and a law 5 firm to write a meta-analysis and a review paper 6 on talc, correct? 7 MR. LOCKE: Objection. 8 THE WITNESS: I don't think I knew that, 9 no. 10 MR. TISI: Okay. Let me show you what I 11 would like to have marked as Exhibit No. 50. 12 (Exhibit No. 50 was marked for 13 identification.) 14 BY MR. TISI: 15 Q And I'm not concerned with the top 16 e-mail because that's not to you, but the bottom 17 e-mail is to you, correct? 18 A Yes. 19 Q Okay. It's from Robert Glenn? 20 MR. LOCKE: Let's let -- 21 MR. TISI: I'm going to. I'm just going 22 to -- 23 MR. LOCKE: -- the witness just read it. 24 MR. TISI: I'm going to have to -- I'm 25 just going to direct her to what it is before we</p>
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<p>1 into who can sit, correct? 2 MR. LOCKE: Objection. 3 THE WITNESS: That is true, but it's 4 also closed in the sense basically they decide on 5 a working group and that's the working group. So 6 are those the best people always? I mean, I think 7 there's that -- there's that question of -- you 8 know, it's like any process, it's -- 9 BY MR. TISI: 10 Q Have you ever seen an unqualified person 11 on an IARC panel? 12 A I -- I mean, I really can't answer that. 13 You know. 14 Q Okay. All right. So IARC review was in 15 2006, correct? 16 A Yes. 17 Q Okay. And they considered the issue, 18 and they found that cosmetic talc would be a 19 possible carcinogen. They looked at the evidence, 20 right? 21 MR. LOCKE: Objection. 22 THE WITNESS: They said limited 23 evidence. 24 BY MR. TISI: 25 Q Okay. But they categorized it as</p>	<p>1 do it, because if she didn't get it, then I'm not 2 going to go there. 3 BY MR. TISI: 4 Q This is an e-mail to you from Robert 5 Glenn. 6 A Okay. 7 Q Do you see that? 8 A Yes. 9 Q And it's dated August 3rd, 19 -- 2005. 10 A Okay. 11 Q Okay. And it's entitled "Rothman 12 Proposal for Updating CTFA Submission on Comments 13 to NTP." Correct? 14 A I'm sorry, where are you? 15 Q It's the subject matter. 16 A Yes. 17 Q Okay. And it's by Crowell & Moring LLP. 18 That's the law firm. 19 A Okay. 20 Q Do you see that? 21 A Yes. 22 Q So why don't you follow Mr. Locke's 23 advice and take a look at it, and I'll ask you 24 some questions. 25 A (Peruses document.)</p>

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<p>1 MR. TISI: Actually, would this be a 2 good time for a break? 3 MS. FRAZIER: Yes. 4 MR. TISI: For you, I will do almost 5 anything. 6 THE VIDEOGRAPHER: All right. Off the 7 record, Counsel? 8 MS. FRAZIER: Thank you. 9 THE VIDEOGRAPHER: The time is 10:43 10 a.m. We're going off the record. 11 (Recess.) 12 THE VIDEOGRAPHER: The time is 10:58 13 a.m., and we are back on the record. 14 BY MR. TISI: 15 Q Dr. Loretz, have you had an opportunity 16 to look at Exhibit No. 50, the e-mail from 17 Mr. Glenn at Crowell & Moring? 18 A Yes. 19 Q And Mr. Glenn worked for Crowell & 20 Moring, but you know that he's a toxicologist, 21 correct? 22 A I probably knew that at the time. 23 Q Okay. And do you know that he was 24 also -- previous to working for the law firm 25 representing Imerys, do you know that he was also</p>	<p>1 cancer." 2 Do you see that? 3 A Yes. 4 Q Okay. So it's talking about two 5 different papers, right? 6 A Yes. 7 Q Okay. So does this refresh your 8 recollection as to whether or not you were aware 9 in the 2000s that Huncharek and Muscat were 10 actually consultants for the law firm representing 11 Imerys, which is -- is Luzenac. 12 A I would say this would refresh my 13 memory, yes. 14 Q Okay. So we have on our chart here in 15 2005 -- 2006 is IARC review, 2005 -- and I'm going 16 to try to write real -- because on a break folks 17 told me my handwriting was abysmal. So we have 18 "Huncharek, Muscat, two papers." One a review 19 and, two, diaphragm. 20 Is that correct? That's what that 21 document says? 22 A What year are you putting that -- 23 Q 2005. 24 A Or it looks those -- yeah, I don't know 25 when -- the publication date, though.</p>
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<p>1 a prior president of the Industrial Minerals 2 Association of North America? 3 A I don't -- that doesn't sound familiar. 4 Q Okay. So it talks to Mark Ellis at IMA 5 North America and to yourself. 6 And I'm interested in the first 7 paragraph. The first paragraph says: "As you may 8 know, we represent Luzenac America in assisting 9 them in preparation of comments to the NTP and 10 IARC regarding carcinogen classification of talc. 11 They have sponsored projects with Drs. Huncharek 12 and Muscat related to reviewing the literature on 13 talc and ovarian cancer, and conducting a 14 meta-analysis of talc and ovarian cancer." 15 Do you see that? 16 A Yes. 17 Q Okay. So two different things, 18 reviewing the literature on talc and conducting a 19 meta-analysis. 20 Do you see that? 21 A Yes. 22 Q Okay. It says: "Both are nearing 23 completion, and in short, the results of the 24 meta-analysis do not find a relationship for usage 25 of talc on contraceptive diaphragms and ovarian</p>	<p>1 Q Right. The publications, actually you 2 know that they -- they actually published two 3 articles bearing on the very same topic 4 subsequently. 5 A Yes, exactly. 6 Q Okay. And I'm going to identify them 7 again to put on our timeline. 8 A Okay. 9 (Exhibit No. 51 was marked for 10 identification.) 11 BY MR. TISI: 12 Q I'm going to attach Exhibit No. 51, 13 which is a meta-analysis on diaphragms. 14 Is that -- and that's dated 2006. I'm 15 sorry, it's dated 2007. Correct? 16 A Correct. 17 Q And I'm going to start using below the 18 line, so it's 2007. And diaphragm publication, 19 I'll write "Huncharek and Muscat." 20 And what exhibit is that? I wrote 21 that -- 22 A 51. 23 (Exhibit No. 52 was marked for 24 identification.) 25 BY MR. TISI:</p>

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<p>1 Q Okay. And then we have Exhibit No. 52</p> <p>2 is a critical review article that they wrote.</p> <p>3 And you're familiar with that article,</p> <p>4 right?</p> <p>5 A Yes.</p> <p>6 Q And when I say you reviewed, you -- you</p> <p>7 were familiar with it, you were familiar with it</p> <p>8 at the time, right?</p> <p>9 A At the time of its --</p> <p>10 Q Publication.</p> <p>11 A I assume --</p> <p>12 Q Or shortly thereafter.</p> <p>13 A Yeah, I assume so, yes.</p> <p>14 Q So 2008, this is the critical review,</p> <p>15 talc and ovarian cancer. And this is 2008. And</p> <p>16 this is Exhibit 52. And that's Huncharek and</p> <p>17 Muscat.</p> <p>18 Okay. And so far we have Dr. Muscat</p> <p>19 appearing in 2000. Correct?</p> <p>20 A Yes.</p> <p>21 Q We have him working on papers in 2005</p> <p>22 for the lawyers representing Imerys, correct?</p> <p>23 A Yes.</p> <p>24 Q Which you were aware of.</p> <p>25 2007, they write a publication. And</p>	<p>1 THE WITNESS: And I guess I would again</p> <p>2 say that independent in the sense that these are</p> <p>3 their conclusions, but -- and submitted on behalf</p> <p>4 of us, which was clear.</p> <p>5 BY MR. TISI:</p> <p>6 Q Right.</p> <p>7 A On behalf of industry.</p> <p>8 Q But they had been long-time consultants</p> <p>9 for the industry. Correct?</p> <p>10 A They had been consulting before then,</p> <p>11 yes.</p> <p>12 Q Okay. For at least 15 -- on talc for at</p> <p>13 least 15, 18 years, correct?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: Where did you come up with</p> <p>16 that? 2000 --</p> <p>17 BY MR. TISI:</p> <p>18 Q 2000 to 2008 -- I'm sorry. 2000 --</p> <p>19 A 2009.</p> <p>20 Q Okay. Let's say nine years, you're</p> <p>21 right. You're right.</p> <p>22 All right. So now let's move forward.</p> <p>23 We talked about IARC.</p> <p>24 So -- now, I want to again fill out the</p> <p>25 timeline so the jury understands what's going on.</p>
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<p>1 then in 2008, they write a publication. And</p> <p>2 2009 -- '8 and '9, they're filing the petition --</p> <p>3 they're drafting the response to the petition as</p> <p>4 a, quote, independent review. Right?</p> <p>5 A Yes.</p> <p>6 Q But the truth of the matter is, as we</p> <p>7 showed on our timeline, is they had been a</p> <p>8 consistent consultant not only for PCPC but for</p> <p>9 other members of the PCPC throughout the 2000s,</p> <p>10 correct?</p> <p>11 MR. LOCKE: Objection.</p> <p>12 THE WITNESS: I mean, they're -- they're</p> <p>13 filing -- the filing that we did came through us.</p> <p>14 That was very clear.</p> <p>15 BY MR. TISI:</p> <p>16 Q Okay. That's a different question.</p> <p>17 Okay. You identified this as an independent</p> <p>18 review, right?</p> <p>19 A That -- yes.</p> <p>20 Q Okay. But when I asked you before are</p> <p>21 you sure they're independent, these -- these two</p> <p>22 scientists had been paid consultants for not only</p> <p>23 PCPC but the industry for at least 15 years before</p> <p>24 this was filed, correct?</p> <p>25 MR. LOCKE: Objection.</p>	<p>1 2008, Dr. Epstein for the Cancer</p> <p>2 Prevention Coalition files -- asks that warnings</p> <p>3 be mandated, correct?</p> <p>4 A Correct.</p> <p>5 Q Your organization files an opposition to</p> <p>6 that in July of 2009, correct?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: Right. We filed saying we</p> <p>9 didn't think those warnings should be mandated.</p> <p>10 BY MR. TISI:</p> <p>11 Q With the FDA.</p> <p>12 A Correct.</p> <p>13 Q Filed -- signed by Dr. Bailey, who used</p> <p>14 to work at the FDA in the very division that would</p> <p>15 be considering the petition, correct?</p> <p>16 A That's correct.</p> <p>17 Q Okay. And do you know whether or not</p> <p>18 any other organizations were even aware of this</p> <p>19 petition to weigh in on it? In other words, are</p> <p>20 you aware of anybody else who filed a response to</p> <p>21 the FDA -- I mean to the Citizen's Petition?</p> <p>22 A I may have known at the time, but I</p> <p>23 don't recall now.</p> <p>24 (Exhibit No. 53 was marked for</p> <p>25 identification.)</p>

27 (Pages 480 to 483)

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<p>1 BY MR. TISI:</p> <p>2 Q All right. I went to the FDA website</p> <p>3 and pulled a copy -- Exhibit 53, I pulled a copy</p> <p>4 of it, and as I read it, the only comment that was</p> <p>5 actually provided was by the PCPC.</p> <p>6 Does that refresh your recollection?</p> <p>7 A As I say, I can't remember, but I have</p> <p>8 no reason not to think that's true.</p> <p>9 Q Okay. And just to kind of fill out a</p> <p>10 timeline because I want to make it clear that I</p> <p>11 don't want to hide anything from the jury here, in</p> <p>12 2015, the petition was denied.</p> <p>13 A That's correct.</p> <p>14 Q So write "2005, FDA," and --</p> <p>15 MR. TISI: Do you have a copy of the</p> <p>16 denial? I'll attach that in a moment.</p> <p>17 BY MR. TISI:</p> <p>18 Q And so from the outside, what the FDA</p> <p>19 had before it was the Epstein petition and the</p> <p>20 PCPC response. Is that -- and then some four</p> <p>21 years later or five years later, it denied the</p> <p>22 petition.</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: Okay.</p> <p>25 BY MR. TISI:</p>	<p>1 A That's true.</p> <p>2 MR. LOCKE: Objection. Beyond the</p> <p>3 scope.</p> <p>4 BY MR. TISI:</p> <p>5 Q That's true, correct?</p> <p>6 A Yes.</p> <p>7 MR. LOCKE: Objection.</p> <p>8 BY MR. TISI:</p> <p>9 Q And just for clarity of the record, the</p> <p>10 denial letter from the FDA dated April 2014 -- I'm</p> <p>11 sorry, it's dated 2014.</p> <p>12 A Yeah, it's '14. I wasn't sure about</p> <p>13 that.</p> <p>14 Q I stated 2015. You know, you're</p> <p>15 correct. You're correct. It's Exhibit No. 54.</p> <p>16 (Exhibit No. 54 was marked for</p> <p>17 identification.)</p> <p>18 BY MR. TISI:</p> <p>19 Q Now, I want to talk about -- now that we</p> <p>20 have our timeline out of the way, I want to talk</p> <p>21 about the Citizen's Petition and the arguments you</p> <p>22 made in them and the circumstances surrounding its</p> <p>23 actual filing. Okay?</p> <p>24 A Yes.</p> <p>25 Q Now, prior to the actual filing of</p>
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<p>1 Q Is that -- is that correct?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: As far as I know, yes. As</p> <p>4 I say --</p> <p>5 BY MR. TISI:</p> <p>6 Q All right. Is there anything -- do you</p> <p>7 know why it took the FDA five years or six years</p> <p>8 to actually act on this petition?</p> <p>9 A I don't. I know that it typically takes</p> <p>10 them years to respond to petitions, but I couldn't</p> <p>11 say anything specific about this one.</p> <p>12 Q Well, petitions related to cosmetics, on</p> <p>13 the scheme of things -- I mean you work with the</p> <p>14 FDA, you know the FDA does a lot of different</p> <p>15 things. It deals with pharmaceutical drugs, it</p> <p>16 deals with over-the-counter drugs, it deals with</p> <p>17 the blood supply, it deals with a lot of different</p> <p>18 things, correct?</p> <p>19 A Not the Office of Cosmetics and Colors,</p> <p>20 but other parts of the FDA, sure.</p> <p>21 Q Right. But the -- but the FDA as a --</p> <p>22 as a whole -- I mean would it be fair to say that</p> <p>23 on a scale of things, cosmetics are not as heavily</p> <p>24 regulated or looked at as is, for example,</p> <p>25 pharmaceutical drugs or over-the-counter drugs?</p>	<p>1 the -- the opposition to this Citizen's Petition,</p> <p>2 we'll just -- can I just call it "the opposition,"</p> <p>3 and we know we're talking about something</p> <p>4 containing the opposition to the Citizen's</p> <p>5 Petition?</p> <p>6 A Yes.</p> <p>7 Q Prior to filing the PCPC's opposition in</p> <p>8 July, and we looked at this earlier, you and --</p> <p>9 when I say "you," I mean you personally -- you and</p> <p>10 your colleagues at the PCPC and the companies</p> <p>11 represented by the lawyers on this table went and</p> <p>12 met with the FDA about the Citizen's Petition,</p> <p>13 correct?</p> <p>14 MR. LOCKE: When?</p> <p>15 THE WITNESS: One other company as well.</p> <p>16 BY MR. TISI:</p> <p>17 Q Unilever.</p> <p>18 A Unilever.</p> <p>19 Q Okay. But certainly Johnson & Johnson</p> <p>20 is by far the biggest contributor to -- in terms</p> <p>21 of resources to the Talc Task Force, correct, in</p> <p>22 terms of money?</p> <p>23 MS. FRAZIER: Objection.</p> <p>24 MR. LOCKE: Objection.</p> <p>25 THE WITNESS: I think what I've seen,</p>

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<p>1 they're the biggest contributor. 2 BY MR. TISI: 3 Q I mean by a factor of a lot, correct? 4 MS. FRAZIER: Object to form. 5 BY MR. TISI: 6 Q I mean, it's a big -- they're the -- 7 they're the major funder of the Talc Task Force, 8 correct? 9 MS. FRAZIER: Object to form. 10 THE WITNESS: But they're not the only 11 funder. 12 BY MR. TISI: 13 Q And in the top two or three is Imerys as 14 well, correct? 15 A That's correct. 16 Q Okay. So -- while there may be many 17 other members of the -- that have an interest in 18 talc, the two big gorillas in the room are J&J, 19 the manufacturer of talcum powder products like 20 Johnson & Johnson's baby powder and Shower to 21 Shower, and the mining company who provides that 22 talc for use in the product, correct? 23 MR. LOCKE: Objection. 24 MS. FRAZIER: Objection to form. 25 THE WITNESS: I mean we have --</p>	<p>1 THE WITNESS: That sounds roughly right 2 from the numbers I've seen. 3 BY MR. TISI: 4 Q Okay. And so the PCPC and Johnson & 5 Johnson and Imerys and Unilever went to go meet 6 with the FDA about the Citizen's Petition, 7 correct? 8 A Yeah, I'm not sure if it was set up 9 specifically about the Citizen's Petition, but I 10 know that certainly got discussed. So yes. 11 Q Well, we'll talk -- we're going to talk 12 about -- have you reviewed those -- those memos 13 before today? 14 A I think I -- I reviewed the memo. I'm 15 not sure what all the discussion went into setting 16 up that meeting, but -- 17 Q Okay. Well, did you -- 18 A -- I don't disagree with that. 19 Q But did you try to investigate that? 20 Because that's an important point. How did that 21 meeting get set up? 22 A I know Dr. Bailey set it up. 23 Q Dr. Bailey, the guy who used to work at 24 the division -- 25 A Correct.</p>
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<p>1 THE REPORTER: Counsel, we can't hear 2 you down here. 3 MS. FRAZIER: No, it's okay. I was 4 just objecting to being called a gorilla. 5 MR. TISI: I'll call you a gorilla, but 6 let's rephrase the question. Okay? 7 BY MR. TISI: 8 Q If you were to rank all of the -- I mean 9 I've seen lists somewhere between 20 and 30 people 10 who make or have an interest in talcum powder 11 products. Correct? 12 A Yes. 13 Q Okay. The major ones if you were to 14 rank them are going to be Johnson & Johnson, 15 correct? 16 A It certainly is one of the companies 17 that has a major interest. There are other 18 companies and they get their say on calls and 19 meetings, et cetera. 20 Q All right. Would it surprise you that 21 between the two of them, they provide -- Imerys 22 and Johnson & Johnson provide between 65 and 70 23 percent of the funding for the talc-related 24 activities of the PCPC? 25 MR. DONATH: Objection to form.</p>	<p>1 Q -- called the division he used to work 2 for to see if he could set up a meeting? 3 A Yes. 4 Q And that meeting occurred in May of 5 2009, correct? 6 A I don't recall, but that sounds about 7 right. 8 Q Okay. So the office -- there was a 9 meeting at the Office of Cosmetics and Colors set 10 up by Dr. Bailey who used to run that division, 11 correct? 12 A Yes. 13 Q And you were at that meeting? 14 A Yes. 15 Q And Dr. Bailey's former subordinate 16 Dr. Katz was at that meeting? 17 A You've said she used to work for him. 18 I -- I have no reason not to believe you, but, 19 yes, she was there. 20 Q Okay. And I'm going to attach 21 Dr. Bailey's report of that meeting, and I think 22 there's an error in it, but I'm going to correct 23 it and see if we can work through it together. 24 This is Exhibit No. 55. 25 (Exhibit No. 55 was marked for</p>

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<p>1 identification.)</p> <p>2 BY MR. TISI:</p> <p>3 Q And just I can correct the error so we</p> <p>4 can correct it going forward. It's from John</p> <p>5 Bailey from Personal Care Council dated Monday,</p> <p>6 May 11th, 2009.</p> <p>7 Do you see that?</p> <p>8 A I'm sorry. The -- oh, yes.</p> <p>9 Q The e-mail.</p> <p>10 A Right, the e-mail.</p> <p>11 Q It's to, among other things, you?</p> <p>12 A Yes.</p> <p>13 Q Okay. And it's a -- meeting notes from</p> <p>14 the meeting of the FDA on talc.</p> <p>15 A Yes.</p> <p>16 Q Okay. And it says: "All: Below are my</p> <p>17 attached notes from the FDA meeting on Friday."</p> <p>18 Correct?</p> <p>19 A Yes.</p> <p>20 Q Okay. And these were recounting a</p> <p>21 note -- notes that happened that prior Friday,</p> <p>22 correct?</p> <p>23 A Yes.</p> <p>24 Q And so the meeting with the FDA says</p> <p>25 May 8th, 2008. Do you see that?</p>	<p>1 predominant number of people at this -- at this</p> <p>2 meeting were from the office that Dr. Bailey ran,</p> <p>3 the Office of Cosmetics and Colors, I was correct?</p> <p>4 A I would say you were correct, yes.</p> <p>5 Q Thank you. I like being correct.</p> <p>6 And you attended that meeting?</p> <p>7 A I did.</p> <p>8 Q Okay. Have you seen the final -- now,</p> <p>9 this is a fairly lengthy, several single-spaced</p> <p>10 pages of notes about what happened at that</p> <p>11 meeting?</p> <p>12 A Okay. Yes.</p> <p>13 Q Do you see that?</p> <p>14 A Yes.</p> <p>15 Q Okay. Have you seen the FDA version</p> <p>16 of -- of that?</p> <p>17 A I think I have in my preparation for</p> <p>18 this.</p> <p>19 Q Well, it says: The action items from</p> <p>20 the meeting. "The FDA has to prepare notes of the</p> <p>21 meeting." It's at the very end, the last</p> <p>22 paragraph.</p> <p>23 A Mm-hmm.</p> <p>24 Q The FDA notes I'm going to show you are</p> <p>25 Exhibit 56.</p>
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<p>1 A Yes.</p> <p>2 Q Okay. Do you agree with me that it's</p> <p>3 likely to be May 8th, 2009?</p> <p>4 A I do agree with you.</p> <p>5 Q Okay. Okay. And in other iterations of</p> <p>6 this I see 2009, but just for the record and for</p> <p>7 our timeline going back to it, the meeting</p> <p>8 happened -- so I'm going to put "FDA meeting."</p> <p>9 And I'm going to do that in red.</p> <p>10 In 2009 -- in May of 2009, right?</p> <p>11 A Yes.</p> <p>12 Q "May '09."</p> <p>13 And when I mentioned attendance for the</p> <p>14 FDA, the Acting Commissioner was there. Do you</p> <p>15 see that?</p> <p>16 A Yes.</p> <p>17 Q Okay. And the director for the Food</p> <p>18 Safety and Applied Nutrition was there. Correct?</p> <p>19 A Yes.</p> <p>20 Q But all the other people there,</p> <p>21 including people that he didn't recognize, were</p> <p>22 from the Office of Cosmetics and Colors?</p> <p>23 A That's what it says, yes.</p> <p>24 Q All right. So when I asked you before</p> <p>25 whether or not this was the primary -- the</p>	<p>1 (Exhibit No. 56 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. TISI:</p> <p>4 Q And the FDA meeting notes is like a</p> <p>5 paragraph and two action items, correct?</p> <p>6 A Yes.</p> <p>7 Q Okay. So the notes that we have of this</p> <p>8 meeting are much more fulsome as recorded by</p> <p>9 Dr. Bailey?</p> <p>10 A Yes.</p> <p>11 Q There's a lot more detail in them.</p> <p>12 A So it appears, yes.</p> <p>13 Q Okay. And I asked you before whether or</p> <p>14 not the purpose of this meeting was to discuss the</p> <p>15 Citizen's Petition. Do you remember that?</p> <p>16 A Yes.</p> <p>17 Q Okay. And the first bullet point, it</p> <p>18 says: "A petition has been submitted by the FDA</p> <p>19 requesting a warning and hearing."</p> <p>20 Do you see that?</p> <p>21 A Yes.</p> <p>22 Q And the first paragraph, full paragraph</p> <p>23 says: "Dr. Katz opened the meeting."</p> <p>24 And Dr. Katz at that point was the</p> <p>25 director of the FDA Division of Cosmetics and</p>

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<p>1 Colors at that point, correct?</p> <p>2 A Yes.</p> <p>3 Q Okay. By saying that: "Counsel had</p> <p>4 requested the meeting, but she wanted to make the</p> <p>5 point that the FDA would not talk about the</p> <p>6 Citizen's Petition on talc as it was still under</p> <p>7 review."</p> <p>8 Do you see that?</p> <p>9 A Actually, I'm sorry, where are you</p> <p>10 exactly? Oh, there we go. Okay.</p> <p>11 Q Do you see that?</p> <p>12 A Yes.</p> <p>13 Q Okay. Do you remember that</p> <p>14 specifically, that she started out saying, you</p> <p>15 know, Great you're all here, but we don't want to</p> <p>16 discuss the Citizen's Petition?</p> <p>17 A I don't remember it, but I -- I accept</p> <p>18 that that is what happened.</p> <p>19 Q Okay. But then Dr. Bailey corrected</p> <p>20 her, and said -- "Dr. Bailey pointed out the</p> <p>21 agenda that was provided was to discuss the</p> <p>22 information related in the petition."</p> <p>23 MR. LOCKE: Objection.</p> <p>24 BY MR. TISI:</p> <p>25 Q Correct?</p>	<p>1 Q It was requested. An agenda was</p> <p>2 provided to the FDA, correct?</p> <p>3 A I think that's what it says. I don't</p> <p>4 recall that, but --</p> <p>5 Q Have you seen the agenda in connection</p> <p>6 with your preparation today?</p> <p>7 A I don't think so.</p> <p>8 Q Okay. I didn't see it either. It might</p> <p>9 be -- it might be around, but I just -- maybe I</p> <p>10 just didn't see it.</p> <p>11 Was anyone -- since the agenda, as</p> <p>12 Dr. Bailey pointed out, was -- involved the</p> <p>13 Citizen's Petition, right?</p> <p>14 A That's what it says, yes.</p> <p>15 Q I'm curious. Did Dr. Bailey propose</p> <p>16 that the guy who wrote the Citizen's Petition be</p> <p>17 invited to the meeting?</p> <p>18 A I don't believe so, no.</p> <p>19 Q Do you know whether or not Dr. Epstein</p> <p>20 or the -- any of the members of the American --</p> <p>21 the Cancer Prevention Coalition were asked to</p> <p>22 attend the meeting by the FDA or suggested by</p> <p>23 PCPC?</p> <p>24 A Not that I'm aware.</p> <p>25 Q I mean you are interested in a fulsome</p>
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<p>1 MR. LOCKE: Objection to form.</p> <p>2 THE WITNESS: Well, that's what it says,</p> <p>3 yes.</p> <p>4 BY MR. TISI:</p> <p>5 Q All right. And in fact, you brought</p> <p>6 with you Dr. Muscat and Dr. Huncharek's</p> <p>7 opposition, the opposition that had not yet been</p> <p>8 filed?</p> <p>9 A It was -- right, it was talked about.</p> <p>10 Q It was talked about, and it was</p> <p>11 summarized for the FDA?</p> <p>12 A Yes, that's what it says.</p> <p>13 Q So the FDA says, We're not going to talk</p> <p>14 about it, but then talked about it.</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: Well, it says that she</p> <p>17 then -- Dr. Katz then clarified to say that you</p> <p>18 can talk about it, but we're not going to discuss</p> <p>19 its status.</p> <p>20 BY MR. TISI:</p> <p>21 Q Okay. So my question to you is, was</p> <p>22 anybody from the --</p> <p>23 Now, this meeting was set up by the --</p> <p>24 by Dr. Bailey at the PCPC, correct?</p> <p>25 A Yes. Or requested, yes.</p>	<p>1 discussion of the science, right?</p> <p>2 A I -- I think for this meeting we were --</p> <p>3 well, I guess the notes speak for themselves.</p> <p>4 Q Well -- okay. My question was, you've</p> <p>5 talked to me before -- you said before when I was</p> <p>6 asking you questions about this petition, you</p> <p>7 said, Well, we didn't think the science supported</p> <p>8 it. Correct?</p> <p>9 A Support the need for a warning, yes.</p> <p>10 Q Right. But we all agreed that there was</p> <p>11 a -- a debate in the medical and scientific</p> <p>12 community about what the science meant, correct?</p> <p>13 A Yes.</p> <p>14 Q And that had been going on for decades,</p> <p>15 correct?</p> <p>16 A Yes.</p> <p>17 Q Okay. And you had a definite point of</p> <p>18 view on the issue, correct?</p> <p>19 A Yes.</p> <p>20 Q On behalf of your members, right?</p> <p>21 A Yes.</p> <p>22 Q And somebody who had a different point</p> <p>23 of view presented a petition to the FDA. Correct?</p> <p>24 A Yes.</p> <p>25 Q And you asked for a meeting at the FDA</p>

<p style="text-align: right;">Page 500</p> <p>1 to discuss, among other things, that petition, 2 correct? 3 A Yes. 4 Q And you actually submitted an agenda. 5 True? 6 A That's what it says. 7 Q And the agenda was clear that you wanted 8 to discuss the petition, correct? 9 A I would assume so based on what this 10 says on the subject matter. 11 Q And you walked in prepared to discuss 12 the petition. You even brought with you 13 Dr. Muscat and Dr. Huncharek's commissioned work 14 on behalf of the industry, correct? 15 A That seems to be what it says, yes. 16 Q And -- well, it's not only what it says, 17 it happened, correct? 18 A Yes. 19 Q And when you're testifying about PCPC -- 20 A Yes. 21 Q -- this is one of the topics you were 22 prepared to talk about. 23 A Okay. 24 Q Right? 25 A Yes.</p>	<p style="text-align: right;">Page 502</p> <p>1 if you were really interested in the scientific 2 question, why not invite the -- why not say, Maybe 3 we should have Dr. Epstein come? 4 A I think we knew where Dr. Epstein stood, 5 and we disagreed with him. 6 Q Right. So why not have him come to 7 present his position? 8 A I don't think this was the meeting for 9 that. 10 Q Okay. And -- the FDA initially 11 expressed its reservation about the meeting, 12 correct? 13 MR. LOCKE: Objection. 14 BY MR. TISI: 15 Q It said -- it said -- initially said 16 that they didn't want to talk about the pending 17 Citizen's Petition, correct? 18 MR. LOCKE: Objection. 19 THE WITNESS: And then said that you can 20 talk to us, but we're not going to talk about -- 21 BY MR. TISI: 22 Q Because you were already there. 23 A Well, they accepted the meeting, though. 24 So if there really was an agenda that -- I'm 25 sure it would have shown that, and they could have</p>
<p style="text-align: right;">Page 501</p> <p>1 Q So you walk in there, and did you say to 2 them, You know, we really want -- this is an 3 important issue, because we agreed that it's an 4 important issue. Ovarian cancer and talc was an 5 important issue, right? 6 A Yes. 7 Q Did you say to them, You know, why don't 8 we get Dr. Epstein to come to this meeting so we 9 can have a fulsome discussion of the pros and cons 10 of what the science means? 11 A I -- I think this was not a meeting 12 where that was -- this was not that meeting. I 13 mean we knew where Dr. Epstein stood. 14 Q Well, they knew where you stood too, 15 but you -- 16 A Right. 17 Q -- you accepted a meeting anyway or you 18 asked for a meeting anyway to discuss the issues, 19 right? 20 A Yes. 21 MR. LOCKE: Objection. Form. 22 THE WITNESS: And they could have said 23 no, but they were willing to meet with us. 24 BY MR. TISI: 25 Q The were willing to meet with you, but</p>	<p style="text-align: right;">Page 503</p> <p>1 said -- I mean they would have asked what -- what 2 did we want to talk about. 3 Q Right. But the first sentence here 4 indicates a little bit of interpreting it fairly, 5 a little bit initial hesitation -- 6 A Sure. 7 Q -- by the FDA to discussing a petition 8 with only one party there and without the other. 9 True? 10 A Well -- 11 MR. LOCKE: Objection. 12 BY MR. TISI: 13 Q True? 14 MR. LOCKE: Objection. 15 THE WITNESS: It's under advisement. I 16 don't know if it's because -- 17 BY MR. TISI: 18 Q I got -- we got to get the objection in, 19 and then you got to answer. 20 A Sorry. 21 Q I'm sorry. Go ahead. I'm sorry. 22 A Just I don't know that -- I think 23 probably their normal policy is they're not going 24 to talk about things that are under advisement. 25 So I don't know that it's because the other party</p>

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<p>1 wasn't there or it's just -- we're working this</p> <p>2 through, so we're not going to -- we're not going</p> <p>3 to give you -- tell you where we stand right now.</p> <p>4 You can talk to us.</p> <p>5 And then later on she asked that we</p> <p>6 submit, formally submit our information, which we</p> <p>7 did.</p> <p>8 Q All right. And asked you some follow-up</p> <p>9 questions, true?</p> <p>10 A Yes.</p> <p>11 Q Okay. Which you did?</p> <p>12 A Yes.</p> <p>13 Q Do you know whether or not the FDA ever</p> <p>14 reached out to Dr. -- Dr. Epstein or anybody else</p> <p>15 to say, Look, you know, we would like to get your</p> <p>16 further input. We met with -- with the industry</p> <p>17 and their trade organization. They raised some</p> <p>18 issues about dose response, about contamination</p> <p>19 with talc, about bio -- with asbestos, about</p> <p>20 biologic plausibility, about all the issues that</p> <p>21 were in the Citizen's Petition. What is your</p> <p>22 response to that?</p> <p>23 Do you know if that was ever done by the</p> <p>24 FDA?</p> <p>25 A I think some of reaching out to us, and</p>	<p>1 A Yes.</p> <p>2 Q Okay. But you wanted to actually get in</p> <p>3 the room and actually speak with them, right?</p> <p>4 A Yes.</p> <p>5 Q Okay. You know, because -- because this</p> <p>6 was important to your members, right?</p> <p>7 A Yes.</p> <p>8 Q Okay. The American Cancer Coalition was</p> <p>9 representing consumers, right?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q Patients?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I'm not sure who they</p> <p>15 represent, but -- yes.</p> <p>16 BY MR. TISI:</p> <p>17 Q Was there anybody in that room on May 8,</p> <p>18 2009, that represented patients, doctors,</p> <p>19 consumers?</p> <p>20 MR. LOCKE: Other than the FDA?</p> <p>21 THE WITNESS: I was going to say the</p> <p>22 Commissioner of the FDA, I would --</p> <p>23 BY MR. TISI:</p> <p>24 Q I'm asking you other than the -- the FDA</p> <p>25 was trying to decide a question. Correct?</p>
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<p>1 the follow-up questions were ones that were</p> <p>2 specific to industry, how do you source talc, that</p> <p>3 kind of thing. So -- so certainly that -- we have</p> <p>4 to be the audience for that.</p> <p>5 Q Right. My question is, do you know</p> <p>6 whether or not in the four or five years between</p> <p>7 the time that you all were meeting with the FDA</p> <p>8 and the time they ultimately came down with a</p> <p>9 conclusion, that anybody from the FDA ever reached</p> <p>10 out to anybody on the other side of the debate and</p> <p>11 said, Now we've heard from industry, we met with</p> <p>12 J&J, we met with Imerys, we had Unilever there, we</p> <p>13 had PCPC there. We have some questions as to what</p> <p>14 this data means too. What is your response to</p> <p>15 that?</p> <p>16 Do you know whether that ever happened?</p> <p>17 A No. But I would say their petition kind</p> <p>18 of speaks, and then we have a response, and then</p> <p>19 again some -- a lot of the industry questions were</p> <p>20 regarding sourcing, the kind of things that were</p> <p>21 real industry-only questions.</p> <p>22 Q But your petition spoke too, right? You</p> <p>23 had a -- you put a 30-page response --</p> <p>24 A Oh yes.</p> <p>25 Q -- by Huncharek and Muscat.</p>	<p>1 A Yes.</p> <p>2 Q A scientific question. Right?</p> <p>3 A Yes.</p> <p>4 Q In fact, Dr. -- in here Dr. -- the</p> <p>5 Acting Commissioner said --</p> <p>6 A Sharfstein.</p> <p>7 Q -- said he had only heard it because of</p> <p>8 some Korean issue, Korean talc sourcing, correct?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I think that's in the</p> <p>11 minutes.</p> <p>12 BY MR. TISI:</p> <p>13 Q Right. It was clear to you that -- that</p> <p>14 they had not been really focused -- at least the</p> <p>15 Commission had not really been focused on the</p> <p>16 issue, correct?</p> <p>17 MR. LOCKE: You mean the Commissioner?</p> <p>18 MR. TISI: I'm asking the Commissioner.</p> <p>19 BY MR. TISI:</p> <p>20 Q You were providing a lot of information</p> <p>21 that they did not have.</p> <p>22 A Again, a lot --</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: -- of our information -- I</p> <p>25 think their questions regarded, again industry,</p>

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<p>1 again sourcing, how do you --</p> <p>2 BY MR. TISI:</p> <p>3 Q That came up too.</p> <p>4 A Right, and that's -- you know, that's</p> <p>5 not a question --</p> <p>6 Q But you came in with the epidemiology --</p> <p>7 the first paragraphs here deal with the</p> <p>8 epidemiology.</p> <p>9 For example, it says: "The Council</p> <p>10 submission and the -- and the Citizen's Petition</p> <p>11 were briefly summarized. The response was</p> <p>12 prepared by two epidemiologists, Dr. Michael</p> <p>13 Huncharek and Dr. Muscat, with a cover letter from</p> <p>14 the Council. In their document Huskarek --</p> <p>15 Huncharek and Muscat provide a summary of each of</p> <p>16 the 12 publications cited in the petition."</p> <p>17 Do you see all that?</p> <p>18 A Yes.</p> <p>19 Q "It was noted that half the publications</p> <p>20 are either reviews or do not provide new data or</p> <p>21 address aspects of ovarian cancer or talc but do</p> <p>22 not provide a link between the two. The</p> <p>23 submission then provides an overall summary of</p> <p>24 epidemiology relating to talc and ovarian cancer,</p> <p>25 noting that the excess risk is small and often not</p>	<p>1 previously worked, correct?</p> <p>2 A That's true.</p> <p>3 Q In fact, that's why you hired him,</p> <p>4 right? You hired him because of experience with</p> <p>5 this particular department.</p> <p>6 A We hired him because of his -- I mean,</p> <p>7 obviously the fact that he had FDA background</p> <p>8 was -- was considered a good thing.</p> <p>9 Q In this department, correct?</p> <p>10 A Yes.</p> <p>11 Q And you hired him knowing full well that</p> <p>12 talc was a very important issue that was coming --</p> <p>13 what that might be dealt with by this department,</p> <p>14 correct?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: As far as I know, and I</p> <p>17 had nothing to do with the hiring of Dr. Bailey,</p> <p>18 it wasn't about a specific issue at all. It</p> <p>19 was -- I mean, the general fact was he had a</p> <p>20 wonderful background with FDA and cosmetics, and</p> <p>21 that made him a valuable employee to the Council,</p> <p>22 to CTFA.</p> <p>23 BY MR. TISI:</p> <p>24 Q Now, do you know whether or not prior to</p> <p>25 this meeting --</p>
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<p>1 statistically significant, overall lacks</p> <p>2 dose-response relationship, or in some cases shows</p> <p>3 an inverse dose-response relationship, lacks a</p> <p>4 biological plausible mechanism, and that the</p> <p>5 exposure data is limited."</p> <p>6 There was a discussion of all that</p> <p>7 stuff, right?</p> <p>8 A I'm not sure there was a discussion. I</p> <p>9 think, as I say, she -- it looks like Dr. Katz</p> <p>10 said, You can tell us -- you can talk to us, but</p> <p>11 we're really not going to engage in a discussion.</p> <p>12 We gave this overall summary, and her</p> <p>13 response was, Well, submit it, and then we can</p> <p>14 consider it fully.</p> <p>15 Q Right. But you were in the room and</p> <p>16 Drs. Epstein and no other doctor who thought on</p> <p>17 the other side of this debate was in the room.</p> <p>18 MR. LOCKE: Objection.</p> <p>19 BY MR. TISI:</p> <p>20 Q Correct?</p> <p>21 A That's correct.</p> <p>22 Q Okay. And also in the room was your</p> <p>23 senior scientific person who knew all of the</p> <p>24 people who he -- or most of the people at the</p> <p>25 Office of Colors and Cosmetics with whom he</p>	<p>1 A This meeting.</p> <p>2 Q This meeting, May 9th -- May 8th --</p> <p>3 A 2009.</p> <p>4 Q -- 2009.</p> <p>5 This was a formal meeting that was set</p> <p>6 up by Dr. Bailey. Correct?</p> <p>7 A I think you would call it that.</p> <p>8 Q Do you know whether this meeting was</p> <p>9 posted to the website so that other people could</p> <p>10 know it was happening, like the American -- the</p> <p>11 Cancer Prevention Coalition?</p> <p>12 A I don't know.</p> <p>13 Q So they -- they wouldn't even know it</p> <p>14 was happening so they could say, Hey, we'd like to</p> <p>15 be in -- we'd like to be in the room?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 BY MR. TISI:</p> <p>18 Q Right?</p> <p>19 A Again, I don't know if it was posted. I</p> <p>20 really don't know.</p> <p>21 Q Do you know whether there were any</p> <p>22 communications with the FDA about this issue</p> <p>23 before this May meeting?</p> <p>24 A I'm not aware.</p> <p>25 Q Have you seen any documents that refer</p>

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<p>1 to a call that was made, conversations that had 2 been had? 3 A From -- related to the petition? 4 Q Mm-hmm. 5 A Sometime between when it was filed 6 and -- 7 Q Mm-hmm. 8 A You can refresh my memory, but 9 nothing -- I'm not thinking of anything, no. 10 (Exhibit No. 57 was marked for 11 identification.) 12 BY MR. TISI: 13 Q Let me show you Exhibit No. 57. 14 This is not a PCPC document. I'm seeing 15 whether this refreshes your recollection. 16 Now, at the very bottom, and I -- I'm 17 going to ask you to read it, but I'm just going to 18 kind of set the table for you. 19 A Very bottom of the second page? 20 Q So first page. 21 A Okay. 22 Q There's an e-mail from Craig Bernard to 23 Mark Zamek at J&J -- I mean at Rio Tinto. And Rio 24 Tinto is -- is Imerys as well, correct? 25 A I believe so, yes.</p>	<p>1 requesting to have a warning label placed on 2 products containing" -- there is no word, but I 3 think it's -- 4 A Right. 5 Q -- involving talc. 6 A Right. 7 Q "Here is an update on that activity. 8 Kathy Wille of J&J informed me that at a recent 9 science meeting in Washington, D.C., she had a 10 side conversation with a key figure from the FDA 11 cosmetic group responsible for responding to the 12 Citizen's Petition. He indicated that the FDA 13 would rule against the petition and would 14 require -- would not require warning labels on 15 cosmetic products, but the FDA is looking for 16 scientific support from industry that would help 17 justify their position. She suggested that there 18 be a collective group working to have comments 19 submitted to the FDA. Principal among these 20 efforts will be comments that Dr. Muscat and 21 Huncharek are co-developing. 22 "In order to orchestrate the completion 23 of these comments, I have been asked by J&J to 24 meet with them, along with Muscat and Huncharek, 25 at their headquarters in New Jersey on Wednesday,</p>
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<p>1 Q And it's referring to a meeting with 2 J&J. Do you see that? 3 A Yes. 4 Q Okay. If you would read it to yourself, 5 please, and then we can -- 6 A Mm-hmm. 7 Q -- we can go off the record if you want. 8 It doesn't matter to me, but you can read it to 9 yourself. 10 MR. TISI: We can go off the record. 11 MR. LOCKE: No. Let's stay on the 12 record. 13 MR. TISI: Okay. 14 THE WITNESS: (Peruses document.) 15 BY MR. TISI: 16 Q I'm really going to ask you about that 17 first big paragraph. 18 A Okay. 19 Q Okay. First of all, the subject matter 20 is "Meeting with J&J," correct? 21 A Yes. 22 Q Okay. And the first sentence says: 23 "You'll recall a couple of months ago we met with 24 a guy Bob Katsioularis' office, and spoke about 25 the Citizen's Petition with the FDA that is</p>	<p>1 November 19th, in order to review the comments 2 before being provided to Personal Care Products 3 Council." 4 Do you see that? 5 A Yes. 6 Q Okay. I read that correctly, right? 7 A I believe so, yes. 8 Q All right. This would suggest that 9 there was another informal contact with the office 10 of colors, fragrance and -- I'm sorry. I'm 11 blanking. Office of -- 12 A Cosmetic and Colors. 13 Q -- Cosmetics and Colors. 14 Are you aware of it? Does this refresh 15 your recollection? 16 MR. LOCKE: Objection. 17 BY MR. TISI: 18 Q Does this refresh your recollection? 19 A No. 20 Q If there was a side conversation about a 21 Citizen's Petition, in your experience being a 22 liaison with the FDA, would that be inappropriate? 23 MR. LOCKE: Objection. 24 MS. FRAZIER: Object to form. 25 MR. LOCKE: Beyond the scope.</p>

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<p style="text-align: right;">Page 516</p> <p>1 THE WITNESS: I -- I mean I'm not a</p> <p>2 liaison with the FDA. I -- I don't know if this</p> <p>3 is referring to the meeting that we had with the</p> <p>4 FDA or a different meeting.</p> <p>5 BY MR. TISI:</p> <p>6 Q Well, the date -- the date of it is</p> <p>7 November 3rd, 2008, so this would have been a good</p> <p>8 six months before your meeting --</p> <p>9 A Oh, okay.</p> <p>10 Q -- with the FDA.</p> <p>11 A Oh, I'm sorry.</p> <p>12 I -- I mean I just can't comment on</p> <p>13 this. I don't know if this happened. I don't</p> <p>14 know if it was -- you know, if it's characterized</p> <p>15 correctly.</p> <p>16 Q Well, I'm going to ask you this</p> <p>17 question. You don't have knowledge of it, I</p> <p>18 accept you at your word.</p> <p>19 If this happened, in your experience</p> <p>20 having side conversations with FDA people about</p> <p>21 issues that are pending before the FDA, is that</p> <p>22 appropriate?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 MS. FRAZIER: Object to form.</p> <p>25 MR. LOCKE: And beyond the scope.</p>	<p style="text-align: right;">Page 518</p> <p>1 it was fairly late -- I mean, I think it was</p> <p>2 reasonably close to when the comments were</p> <p>3 submitted.</p> <p>4 BY MR. TISI:</p> <p>5 Q Do you know?</p> <p>6 A No.</p> <p>7 Q Did you investigate that?</p> <p>8 I mean, one of the categories very</p> <p>9 specific in our notice of deposition were the</p> <p>10 circumstances surrounding the Citizen's Petition.</p> <p>11 Did you -- that's why I asked you in the early --</p> <p>12 A Mm-hmm.</p> <p>13 Q Did you interview or look specifically</p> <p>14 at the notes pertaining to the Citizen's Petition</p> <p>15 and perhaps speak to Dr. Bailey about what</p> <p>16 happened?</p> <p>17 A Did I speak to him at the time?</p> <p>18 MR. LOCKE: Objection. It's a compound</p> <p>19 question.</p> <p>20 BY MR. TISI:</p> <p>21 Q Okay. Did you review all the documents</p> <p>22 at your possession relating to the preparation of</p> <p>23 the Citizen's Petition?</p> <p>24 A In preparation for this?</p> <p>25 Q Yes.</p>
<p style="text-align: right;">Page 517</p> <p>1 THE WITNESS: I can't imagine an FDA</p> <p>2 person saying something like -- I mean that would</p> <p>3 seem to me --</p> <p>4 BY MR. TISI:</p> <p>5 Q Wrong.</p> <p>6 A -- nothing I've ever seen.</p> <p>7 Q And it would be wrong, right?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 MS. FRAZIER: Object to form.</p> <p>10 MR. LOCKE: Beyond the scope.</p> <p>11 THE WITNESS: Again, I don't know if</p> <p>12 this is properly characterized or under- -- what</p> <p>13 the understanding was.</p> <p>14 BY MR. TISI:</p> <p>15 Q Okay. All right. Now, before we</p> <p>16 discuss the FDA meeting any further from May of</p> <p>17 2009, and the industry interpretation of evidence</p> <p>18 actually filed in the white paper, when -- let's</p> <p>19 talk about what happened before.</p> <p>20 The petition was filed in the spring of</p> <p>21 2008. Do you know when it was that Dr. Bailey was</p> <p>22 first contacted by J&S to participate in this</p> <p>23 process?</p> <p>24 MR. LOCKE: Objection to form.</p> <p>25 THE WITNESS: I don't. I mean, I think</p>	<p style="text-align: right;">Page 519</p> <p>1 A I'm not sure.</p> <p>2 Q All right. Did you ask to see the notes</p> <p>3 from the other defendants that might help you</p> <p>4 understand better what PCPC's role with respect to</p> <p>5 the Citizen's Petition was?</p> <p>6 A No.</p> <p>7 Q Okay. This is --</p> <p>8 MR. LOCKE: Let me just -- I want to</p> <p>9 clarify, to the extent they were produced.</p> <p>10 BY MR. TISI:</p> <p>11 Q Okay. Like, for example, that one that</p> <p>12 we just showed involved the Citizen's Petition.</p> <p>13 Had you ever seen that before?</p> <p>14 A I -- no.</p> <p>15 Q Okay. Did you speak to -- I mean the</p> <p>16 two people that were involved in the process, as</p> <p>17 best as I can tell, from PCPC were you and</p> <p>18 Dr. Bailey. Right?</p> <p>19 A That's probably correct, yes.</p> <p>20 Q Did you speak to Dr. Bailey?</p> <p>21 A No.</p> <p>22 Q So you don't know what -- what</p> <p>23 communications he had, do you?</p> <p>24 A I --</p> <p>25 MR. LOCKE: Objection.</p>

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<p style="text-align: right;">Page 520</p> <p>1 THE WITNESS: I can tell you what I 2 think my recollection is, that this was not a 3 longstanding thing. This was a -- J&J had -- had 4 worked on having a -- Drs. Muscat and Huncharek 5 prepare a review, a current review of the 6 literature, and thought that that would be 7 appropriate to submit. And I suspect that all 8 happened fairly soon before we actually submitted 9 it. 10 BY MR. TISI: 11 Q Now, prior to this you had fairly 12 consistent -- on this issue, you were -- as best I 13 can tell from looking at the overall records that 14 were produced in this case, and you can correct me 15 if I'm wrong, as I look at the decade or so prior 16 to this, you were the primary contact on this 17 issue. 18 A I would say myself and Dr. McEwen. 19 Q Okay. Dr. Bailey really wasn't hands on 20 with this issue over the -- as compared to you, 21 correct? 22 A Well, I guess I think our -- you know, 23 our biggest involvement, PCPC's biggest 24 involvement, biggest effort related to NTP, and 25 Dr. Bailey wasn't there at the time.</p>	<p style="text-align: right;">Page 522</p> <p>1 Q So let me show you an e-mail dated -- 2 58, this is May 2008, right after the Citizen's 3 Petition was filed. It's an internal -- this 4 would have been a whole year before the meeting at 5 the -- at the FDA. 6 And from Kathleen Wille, and it's an 7 internal document. I don't expect that you would 8 have seen it in realtime. But it's talking about 9 the Citizen's Petition and the next steps. 10 Do you see it? 11 A I'm just reading through now. 12 (Peruses document.) Okay. 13 Q Okay. And so just as you read this, 14 what's happening is the Citizen's Petition is 15 filed by Dr. Epstein, and there's kind of a 16 mobilization of effort in -- in how to respond to 17 that, and it's entitled "Next Steps." Do you see 18 that? 19 A I'm not sure where -- 20 Q Second page. 21 A Yes. 22 Q Okay. And underneath that, one of the 23 things they -- two things -- there are three 24 things they identify. Secure funding and engage 25 experts, and that would be Huncharek and Muscat</p>
<p style="text-align: right;">Page 521</p> <p>1 Q Okay. And the Citizen's Petition as 2 well. 3 A Right, but it -- it wasn't -- we weren't 4 doing multiple submissions and presenting at 5 meetings, and that sort of stuff. So it was -- 6 Q Right. But in terms of -- and, you 7 know, we looked at examples here, but, you know, 8 you were kept up to date on the IARC issues, you 9 had been communicating with Bob Glenn at -- at -- 10 I mean I've seen a bunch of them, I could pull 11 them out for you. 12 But to the extent that the -- the other 13 defendants in this case, J&J and Imerys, were 14 contacting PCPC about issues related to talc, you 15 were prime -- the primary person that would be 16 their liaison. 17 A Probably. That's probably true. 18 Q Okay. Until the Citizen's Petition 19 was -- was filed, do you know that they 20 contacted -- they wanted to contact Dr. Bailey? 21 MR. LOCKE: Objection. 22 THE WITNESS: No, I didn't. 23 (Exhibit No. 58 was marked for 24 identification.) 25 BY MR. TISI:</p>	<p style="text-align: right;">Page 523</p> <p>1 that's named here, and PCPC ultimately paid for 2 that, right? 3 A Yes. 4 Q Okay. Number 2, "Engage internal 5 stakeholders." Do you know whether or not any 6 public relations people were -- were contacted in 7 connection with the Citizen's Petition? 8 A I'm not aware -- 9 MR. LOCKE: Objection. You're referring 10 to J&J -- you're asking the witness about J&J? 11 MR. TISI: No, I did not. 12 BY MR. TISI: 13 Q I asked, are you aware of any public 14 relations people for anybody that was contacted in 15 connection with this Citizen's Petition? 16 A I guess I could only answer for PCPC, 17 and I'm not aware of any. 18 Q Okay. But the third is what I'm most 19 interested in, "Determine level of external 20 support." 21 The first is John Bailey. It says: 22 "John Bailey of the Personal Care Products Council 23 is out of the office until the next week, 24 June 2nd. We will ascertain their plans to 25 respond."</p>

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<p style="text-align: right;">Page 524</p> <p>1 Do you see that?</p> <p>2 A Yes.</p> <p>3 Q Okay. It didn't say, We're contacting</p> <p>4 Linda Loretz, are they?</p> <p>5 A That might be because it's Kathy Wille.</p> <p>6 I mean it just kind of depends who within</p> <p>7 Johnson & Johnson is -- is responding.</p> <p>8 Q So do you know whether or not in this</p> <p>9 time frame -- this is a full year before the</p> <p>10 meeting, more than -- with the FDA and more than a</p> <p>11 year before the formal response was filed in July</p> <p>12 of 2009.</p> <p>13 Do you know whether or not at this time</p> <p>14 frame, J&J had been able to contact Dr. Bailey,</p> <p>15 who again had been the prior director of the</p> <p>16 division?</p> <p>17 A Yeah, I don't know what discussions went</p> <p>18 on with --</p> <p>19 Q I don't mean to be factitious about it,</p> <p>20 but wouldn't it make sense to actually -- if you</p> <p>21 are here to testify on that issue, to actually</p> <p>22 speak to Dr. Bailey --</p> <p>23 MR. LOCKE: Objection.</p> <p>24 BY MR. TISI:</p> <p>25 Q -- about that issue?</p>	<p style="text-align: right;">Page 526</p> <p>1 Counsel.</p> <p>2 MR. LOCKE: Okay, good.</p> <p>3 BY MR. TISI:</p> <p>4 Q Tell me everything that you know</p> <p>5 happened with respect to the development of the</p> <p>6 response to the Citizen's Petition.</p> <p>7 I know you said it was initiated by J&J.</p> <p>8 Do you know that Imerys had some input -- we saw a</p> <p>9 meeting that -- with Drs. Huncharek and Muscat</p> <p>10 and -- and Imerys in November. Were you at that</p> <p>11 meeting?</p> <p>12 A No.</p> <p>13 Q You know -- did you know it happened?</p> <p>14 A I don't believe so. If I -- I don't</p> <p>15 recall it, no.</p> <p>16 Q Were you given an opportunity to review</p> <p>17 the -- the Citizen's Petition that was actually</p> <p>18 filed on -- on PCPC's behalf?</p> <p>19 A I -- I'm sure I was in the sense that</p> <p>20 obviously if it was something we have had an issue</p> <p>21 with, we wouldn't have submitted it. So I'm going</p> <p>22 to say yes.</p> <p>23 Q And so when you say it was -- it was</p> <p>24 drafted by somebody else, it went out under PCPC's</p> <p>25 name, and to the extent that you're here as a</p>
<p style="text-align: right;">Page 525</p> <p>1 MR. LOCKE: Objection.</p> <p>2 By the way, it also says, "We will then</p> <p>3 ascertain their plans."</p> <p>4 MR. TISI: I understand.</p> <p>5 THE WITNESS: I mean, I don't think we</p> <p>6 did anything on the petition until later, so I</p> <p>7 kind of read into that that there was not a lot</p> <p>8 going on at this point.</p> <p>9 BY MR. TISI:</p> <p>10 Q Well, there was -- there's a couple of</p> <p>11 things, right, that could go on? Number one is</p> <p>12 actually responding to the petition. Number two</p> <p>13 could actually be speaking to the FDA.</p> <p>14 Do you know whether or not in this time</p> <p>15 frame Dr. Bailey had spoken to anybody at the FDA?</p> <p>16 A I'm not aware that he had.</p> <p>17 Q And you've never taken the time</p> <p>18 before -- before today, and we've had -- this is</p> <p>19 the second day of deposition. You've had</p> <p>20 depositions in other cases. You've never spoken</p> <p>21 to him about this issue?</p> <p>22 A No.</p> <p>23 MR. LOCKE: You're welcome to show her a</p> <p>24 document if it -- can refresh her recollection.</p> <p>25 MR. TISI: I'm sure I know the rules,</p>	<p style="text-align: right;">Page 527</p> <p>1 representative of PCPC, you agree with everything</p> <p>2 that's in that document.</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: What I'm saying is -- when</p> <p>5 you say "drafted by somebody else," I mean it was</p> <p>6 drafted by epidemiologists. So --</p> <p>7 BY MR. TISI:</p> <p>8 Q Right. With the input of Imerys and</p> <p>9 J&J, correct?</p> <p>10 A Well, I think -- I mean they're speaking</p> <p>11 for themselves.</p> <p>12 Q But -- but --</p> <p>13 A I take that at face value.</p> <p>14 Q But the report was actually --</p> <p>15 MR. LOCKE: Let her finish her answer,</p> <p>16 please.</p> <p>17 BY MR. TISI:</p> <p>18 Q You don't know what happened at the</p> <p>19 meeting in -- in November when -- when Dr. Muscat</p> <p>20 and Huncharek went to Skillman, New Jersey, and</p> <p>21 met with J&J and Imerys, correct?</p> <p>22 A Because I wasn't there. I mean, I can</p> <p>23 read the -- the submission. So --</p> <p>24 Q Right. And you don't know what edits</p> <p>25 were made to the original document, do you?</p>

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<p style="text-align: right;">Page 528</p> <p>1 MS. FRAZIER: Object to form.</p> <p>2 THE WITNESS: No.</p> <p>3 BY MR. TISI:</p> <p>4 Q And when a -- when a company -- I mean,</p> <p>5 when a company commissions a report like this,</p> <p>6 doesn't the company usually reserve the right to</p> <p>7 review it and make comments and edits before it's</p> <p>8 submitted?</p> <p>9 MR. LOCKE: Objection. Beyond the</p> <p>10 scope.</p> <p>11 BY MR. TISI:</p> <p>12 Q Typically?</p> <p>13 A I mean that --</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: -- that brings up like us</p> <p>16 doing that, PCPC, you know, talc, other topics,</p> <p>17 whatever, and yes, but I think when you're hiring</p> <p>18 reputable people, they're not going to let you</p> <p>19 change their conclusions. I mean, you might have</p> <p>20 edits, typos, clarity needed. I mean...</p> <p>21 BY MR. TISI:</p> <p>22 Q Right. Focus.</p> <p>23 A Yeah.</p> <p>24 Q Right. But -- but -- I mean that</p> <p>25 presumes that these are reputable people in part,</p>	<p style="text-align: right;">Page 530</p> <p>1 that says "Meta-Analysis Research Group" across</p> <p>2 the top, right?</p> <p>3 A Yes.</p> <p>4 Q Okay. Did you do any due diligence as</p> <p>5 to -- as to who Meta-Analysis Research Group was?</p> <p>6 MR. LOCKE: Objection. Asked and</p> <p>7 answered.</p> <p>8 THE WITNESS: We put faith in the</p> <p>9 epidemiologists as knowledgeable epidemiologists.</p> <p>10 BY MR. TISI:</p> <p>11 Q Okay. Without doing your due diligence.</p> <p>12 MR. LOCKE: Objection.</p> <p>13 BY MR. TISI:</p> <p>14 Q You did not investigate Dr. Huncharek</p> <p>15 and Muscat and what their relationship was, where</p> <p>16 their funding came from, and how much time they</p> <p>17 spent on these issues, did you?</p> <p>18 MR. LOCKE: Objection. Mischaracterizes</p> <p>19 testimony, asked and answered.</p> <p>20 THE WITNESS: We accepted them because</p> <p>21 of their epidemiology expertise.</p> <p>22 BY MR. TISI:</p> <p>23 Q Did you have an opportunity to review</p> <p>24 this before it went in?</p> <p>25 A As I say, I'm sure I did.</p>
<p style="text-align: right;">Page 529</p> <p>1 don't you think?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: It does.</p> <p>4 BY MR. TISI:</p> <p>5 Q Did you -- did you do -- I mean that's</p> <p>6 why I brought the brochure out there. You didn't</p> <p>7 do any due diligence as to who these people were</p> <p>8 and what their stake was in this issue, did you?</p> <p>9 MR. LOCKE: Objection. Mischaracterizes</p> <p>10 testimony.</p> <p>11 THE WITNESS: Yeah.</p> <p>12 MR. TISI: Whose testimony?</p> <p>13 MR. LOCKE: Hers.</p> <p>14 BY MR. TISI:</p> <p>15 Q Did you do any due diligence into who</p> <p>16 Meta-Analysis Research Group is and to where they</p> <p>17 got their major funding?</p> <p>18 MR. LOCKE: Objection. Asked and</p> <p>19 answered. We've covered this.</p> <p>20 BY MR. TISI:</p> <p>21 Q Did you do it?</p> <p>22 A We had worked with Dr. Muscat before.</p> <p>23 Q I -- I didn't ask you that question.</p> <p>24 This was written on behalf of Meta-Analysis</p> <p>25 Research Group, correct? It's got the big logo</p>	<p style="text-align: right;">Page 531</p> <p>1 Q Okay. Have you had any -- do you have</p> <p>2 any dispute that this is PCPC's response, that</p> <p>3 PCPC agrees with the content?</p> <p>4 MR. LOCKE: Objection. Asked and</p> <p>5 answered. The witness testified it was submitted</p> <p>6 by the two epidemiologists.</p> <p>7 MR. TISI: I -- I'm not going to ask you</p> <p>8 to characterize it. Your not under oath, Counsel.</p> <p>9 I appreciate you schooling me, but honestly.</p> <p>10 BY MR. TISI:</p> <p>11 Q Is this PCPC's document?</p> <p>12 MR. LOCKE: We're just going to stick</p> <p>13 with the prior answer then.</p> <p>14 BY MR. TISI:</p> <p>15 Q Is this PCPC's document?</p> <p>16 MR. LOCKE: Objection. Asked and</p> <p>17 answered. Let's move on.</p> <p>18 MR. TISI: No, we're not moving on. I</p> <p>19 want an answer to that question.</p> <p>20 MR. LOCKE: You've answered -- she's</p> <p>21 answered it three times.</p> <p>22 BY MR. TISI:</p> <p>23 Q Do you -- do you -- is this PCPC's -- I</p> <p>24 mean, for example, we read a sentence at the very</p> <p>25 beginning in the Introduction section that says,</p>

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<p style="text-align: right;">Page 532</p> <p>1 We --</p> <p>2 MR. LOCKE: You're talking about the</p> <p>3 instruction that was written by the two</p> <p>4 scientists?</p> <p>5 MR. TISI: The -- I don't know if that's</p> <p>6 written by the two scientists. That's my</p> <p>7 question.</p> <p>8 MR. LOCKE: Well, it says "prepared" --</p> <p>9 MR. TISI: Honestly, Counsel.</p> <p>10 MR. LOCKE: No, honestly.</p> <p>11 MR. TISI: Honestly, I'm asking the</p> <p>12 question. Okay. There's been a lot of</p> <p>13 ghostwriting in this case.</p> <p>14 MR. LOCKE: Objection.</p> <p>15 BY MR. TISI:</p> <p>16 Q "Given the multiple implications of such</p> <p>17 warnings, the Personal Care Products Council</p> <p>18 sought an evaluation of the validity of the</p> <p>19 scientific facts underlying this request." Right?</p> <p>20 Do you know whether or not this</p> <p>21 document, Exhibit No. 20 -- 43, is the report</p> <p>22 submitted by PCPC and it is PCPC's position,</p> <p>23 correct?</p> <p>24 MR. LOCKE: Objection. Compound</p> <p>25 question.</p>	<p style="text-align: right;">Page 534</p> <p>1 Q Not a hundred percent consistent, but</p> <p>2 is --</p> <p>3 A But, yes.</p> <p>4 Q -- is a hundred percent consistency</p> <p>5 required?</p> <p>6 A No.</p> <p>7 Q Okay. So there was consistency across</p> <p>8 studies.</p> <p>9 Now, arguing against causal association,</p> <p>10 Dr. Bailey, on behalf of the PCPC, which you are</p> <p>11 here for --</p> <p>12 A Yes.</p> <p>13 Q -- says: "There is a lack of a clear</p> <p>14 dose-response relationship." Correct?</p> <p>15 A Yes.</p> <p>16 Q And even posits that some epidemiologic</p> <p>17 studies suggest an inverse association. Correct?</p> <p>18 A Correct.</p> <p>19 Q Now, as a toxicologist, if you see an</p> <p>20 inverse association with the disease, doesn't it</p> <p>21 raise the suggestion that this is a protective --</p> <p>22 may have a protective effect?</p> <p>23 MR. LOCKE: Objection. Beyond the</p> <p>24 scope, calls for expert testimony.</p> <p>25 BY MR. TISI:</p>
<p style="text-align: right;">Page 533</p> <p>1 THE WITNESS: I believe this is the</p> <p>2 document we submitted.</p> <p>3 BY MR. TISI:</p> <p>4 Q Okay. All right. Let's talk about it</p> <p>5 for a moment.</p> <p>6 The summary provided by Dr. Bailey in</p> <p>7 the cover letter says: "The review concludes that</p> <p>8 the weak epidemiologic association is unlikely to</p> <p>9 be causal."</p> <p>10 Do you see that?</p> <p>11 A Yes.</p> <p>12 MR. LOCKE: What page are you at?</p> <p>13 MR. TISI: Page 2, Dr. Bailey's letter.</p> <p>14 MR. LOCKE: Okay.</p> <p>15 BY MR. TISI:</p> <p>16 Q Putting aside the characterization of</p> <p>17 "weak," which we can talk about in a moment, do</p> <p>18 you believe that there was an epidemiologic</p> <p>19 association seen across studies?</p> <p>20 A It's not --</p> <p>21 MR. LOCKE: Objection. Beyond the</p> <p>22 scope.</p> <p>23 THE WITNESS: Not a hundred percent</p> <p>24 consistent, no.</p> <p>25 BY MR. TISI:</p>	<p style="text-align: right;">Page 535</p> <p>1 Q I mean there might be reasons why</p> <p>2 that -- why that is seen, correct?</p> <p>3 MR. LOCKE: Same objection.</p> <p>4 THE WITNESS: In theory, that's possible</p> <p>5 if there's consistency.</p> <p>6 BY MR. TISI:</p> <p>7 Q I mean if this was a protective of</p> <p>8 ovarian cancer, you may have found a miracle,</p> <p>9 right?</p> <p>10 A Well, I would go into the causality. It</p> <p>11 would work the same way for protective effect.</p> <p>12 Q You didn't believe that there was an</p> <p>13 inverse -- there was an inverse relationship</p> <p>14 between ovarian cancer and talc, did you?</p> <p>15 A That's not what it says. Some</p> <p>16 studies --</p> <p>17 Q Suggest that.</p> <p>18 A -- showed that.</p> <p>19 Q And if that were really something that</p> <p>20 was seen in some studies, as a toxicologist and as</p> <p>21 somebody who represents the talc industry, that</p> <p>22 would be something that would be really an</p> <p>23 interest to you, wouldn't it?</p> <p>24 A I don't read it that way at all. The</p> <p>25 point of saying that some studies showed an</p>

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<p style="text-align: right;">Page 536</p> <p>1 inverse relationship cast doubt on the causality. 2 Q Okay. Well, there are biases that might 3 suggest that -- why that would occur particularly 4 with a disease like cancer. Are you familiar with 5 survival bias? Have you ever heard of that? 6 MR. LOCKE: Objection. Beyond the 7 scope. 8 THE WITNESS: I'm not sure what that 9 phrase means. 10 BY MR. TISI: 11 Q Okay. Did you ever -- on behalf of the 12 PCPC, did you ever ask whether or not there would 13 be explanations consistent with causation by which 14 you might see an inverse dose-response 15 relationship? 16 A I think -- I mean, as far as the 17 scientist- -- the scientific analysis we left to 18 the epidemiologists. 19 Q Well, I mean, pardon me for being -- for 20 being direct about this. 21 Before this was actually filed, you and 22 all of these -- these companies marched into the 23 FDA on the Citizen's Petition issue on May -- in 24 May of 2009 to talk about the epidemiology in 25 part. Correct?</p>	<p style="text-align: right;">Page 538</p> <p>1 Q -- that are different than the 2 explanation that Drs. Muscat and Huncharek said on 3 the -- on behalf of the industry. 4 A I think our -- 5 MR. LOCKE: Objection. 6 THE WITNESS: I think our comments were 7 posted, though, so somebody could see that they 8 were -- 9 BY MR. TISI: 10 Q Do you know whether or not Dr. Epstein 11 or anybody else was contacted and say, These 12 are -- these are the contacts. Do you want to 13 respond? Do you know whether they even checked 14 the website? 15 A Well, I don't, but they had the right to 16 check -- I mean -- 17 Q Right. 18 A -- the same way as a Citizen Petition 19 would be posted, the comments received would be 20 posted. 21 Q But not everybody has a former director 22 of the division that considers this work for them 23 like you did, correct? 24 MR. LOCKE: Objection. 25 BY MR. TISI:</p>
<p style="text-align: right;">Page 537</p> <p>1 A I think the talk on that was fairly 2 limited. I mean, the parts I remember from that 3 meeting had more to do with talking about sourcing 4 and that sort of thing. I -- and again, as -- as 5 the meeting minutes say, FDA wasn't engaging us in 6 discussion. They were going to let us say our 7 piece -- 8 Q Right. 9 A -- and then said, Please submit that so 10 that we can actually read and consider it. 11 Q And there was no opportunity for 12 doctor -- Dr. Epstein or anybody else to come in 13 and say, You know, okay, we saw that in the -- in 14 the medical literature. This is a possible 15 explanation as to why that is. 16 MR. LOCKE: Objection. 17 BY MR. TISI: 18 Q There was no other opportunity in the 19 four years that this was pending for -- for 20 anybody to come in and say -- and say, You know 21 what, we -- we noted that there's an inverse 22 relationship, but these are possible explanations 23 for that -- 24 MR. LOCKE: Objection. 25 BY MR. TISI:</p>	<p style="text-align: right;">Page 539</p> <p>1 Q Do you know whether or not Epstein had 2 any connection with the FDA? 3 I mean, you have to admit having 4 Dr. Bailey is a pretty -- is a pretty important 5 connection to the FDA, don't you think? 6 MR. LOCKE: Stop. Which question do you 7 want her to answer? 8 MR. TISI: That one. 9 BY MR. TISI: 10 Q That's a pretty important connection to 11 the FDA, having somebody who worked for the 12 division, correct? 13 MR. LOCKE: Objection. 14 THE WITNESS: I mean, I think as I said 15 before, he was -- he was hired for his 16 understanding of the FDA, for his experience. 17 BY MR. TISI: 18 Q Not his contacts? 19 A For knowing the people, that's -- that's 20 okay. That doesn't mean they're going to -- 21 Q Right. 22 A -- do things differently because they 23 know the guy. 24 Q Do you know -- do you know whether or 25 not Dr. Epstein's group had any similar</p>

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<p>1 relationship with the FDA?</p> <p>2 A I -- I do not.</p> <p>3 Q So the next thing that Dr. Bailey on</p> <p>4 behalf of the PCPC says that: A plausible</p> <p>5 econom- -- biologic mechanism is lacking to</p> <p>6 explain a causal relationship."</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q It talks about potential confounding</p> <p>10 factors, correct?</p> <p>11 A Yes.</p> <p>12 Q And it talks about -- summarizes all</p> <p>13 of -- all of the issues?</p> <p>14 A Yes.</p> <p>15 Q All right. Now, one of the things that</p> <p>16 the FDA was very concerned about at the meeting</p> <p>17 that you attended with them was whether or not</p> <p>18 cosmetic talc --</p> <p>19 The stuff that comes in the bottle,</p> <p>20 right?</p> <p>21 A Yes.</p> <p>22 Q -- had constituents that might explain</p> <p>23 the increased relative risks. They talk about</p> <p>24 asbestos, correct -- for example, correct?</p> <p>25 A I think they talked about purity, yes.</p>	<p>1 "An additional limitation on existing literature</p> <p>2 with the proposed talc/ovarian cancer association</p> <p>3 is a lack of any known biological mechanism."</p> <p>4 Do you see that?</p> <p>5 A I'm sorry. Okay. Now I'm -- on the</p> <p>6 right paragraph, I think. Yes.</p> <p>7 Q Okay. Next paragraph down, and feel</p> <p>8 free to read it if you wish. I'm not -- I assume</p> <p>9 you read this before you came in here today,</p> <p>10 right?</p> <p>11 A Yes.</p> <p>12 Q Okay. "He makes the point that</p> <p>13 initially Cramer, et al.," -- and that's</p> <p>14 Dr. Cramer we talked about before who published</p> <p>15 epidemiology -- several epidemiology studies, in</p> <p>16 fact, right?</p> <p>17 A Yes.</p> <p>18 Q He's one of the people who looked at the</p> <p>19 medical literature and thought there was a causal</p> <p>20 inference, right?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. TISI:</p> <p>24 Q Okay.</p> <p>25 -- "and sought to draw an analogy</p>
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<p>1 Q Okay. And -- and that's an important</p> <p>2 issue, don't you think?</p> <p>3 A Sure.</p> <p>4 Q And one of the things that has made the</p> <p>5 points that is made by Dr. Bailey on behalf of the</p> <p>6 PCPC and Dr. Muscat and Huncharek is that there</p> <p>7 was no biologically plausible mechanism because</p> <p>8 talc is not known to be a carcinogen, pure talc.</p> <p>9 A Okay.</p> <p>10 Q Is that true? I mean, I could point it</p> <p>11 out. Let's go to the page -- let's go. Go to</p> <p>12 page 25 of the -- of Dr. Huncharek's report --</p> <p>13 Muscat and Huncharek's report.</p> <p>14 A Okay.</p> <p>15 Q Could you read -- let's put up the last</p> <p>16 two paragraphs.</p> <p>17 Are you there? It's page 25 of -- 28 of</p> <p>18 39.</p> <p>19 Okay. Now it says here: "Initially</p> <p>20 Cramer," and that's --</p> <p>21 A What page are you on?</p> <p>22 Q Page 20 -- it's 25 on the top. It says</p> <p>23 28 of 39.</p> <p>24 A 28. Okay. Got it.</p> <p>25 Q And the third paragraph down, it says:</p>	<p>1 between talc and fibrous asbestos, the latter</p> <p>2 being a known and well-described carcinogen."</p> <p>3 First of all, that's true, right?</p> <p>4 A I'm sorry. I'm --</p> <p>5 MR. LOCKE: What's your question?</p> <p>6 BY MR. TISI:</p> <p>7 Q I said -- I said asbestos -- "fibrous</p> <p>8 asbestos is a known and well-described</p> <p>9 carcinogen."</p> <p>10 A Where does it say that?</p> <p>11 Q First sentence, the last full paragraph</p> <p>12 starting "Initially."</p> <p>13 A Okay. Oh, okay it. Got it. Sorry.</p> <p>14 Very first sentence.</p> <p>15 Q And you agree with that, right, because</p> <p>16 you sent that --</p> <p>17 A Yes.</p> <p>18 Q -- on behalf of the PCPC? Okay.</p> <p>19 And he makes the point at the end that:</p> <p>20 "Prior to the 1970s, some products may have</p> <p>21 contained some asbestos." Correct?</p> <p>22 A Correct.</p> <p>23 Q And that's an argument you've heard over</p> <p>24 and over and over again, right?</p> <p>25 A Yes.</p>

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<p>1 Q Okay. And it says: "Clearly such 2 products could possibly represent a carcinogenic 3 risk secondary to asbestos contamination." 4 Correct? 5 A That's what it says. 6 Q Okay. And so we can agree that asbestos 7 contamination could in fact be a basis of talcum 8 powder products -- a biologically plausible 9 mechanism by which talcum powder products may 10 cause ovarian cancer. Correct? 11 MR. LOCKE: Objection. Beyond the 12 scope. 13 THE WITNESS: Yeah, I mean, I think what 14 this is actually saying is -- is that's not talc 15 per se. 16 BY MR. TISI: 17 Q Right. But we're talking about -- 18 that's why I made the point in the very beginning 19 of saying that -- we're talking about what's in 20 the bottle, right? 21 A Right. 22 Q And so if talcum powder products have 23 asbestos in it, that would be a biologically 24 plausible mechanism, and Drs. Huncharek and Muscat 25 assumed that there was none. That was a predicate</p>	<p>1 BY MR. TISI: 2 Q Okay. No detectable asbestos or no 3 asbestos? 4 A I mean, there is a specification that's 5 no detectable. 6 Q Different question. 7 My question is, are you representing to 8 the -- is this being represented to the FDA that 9 there is -- that asbestos was eliminated? 10 A I mean, I think the FDA knows as much 11 about what's going on with asbestos because they 12 were involved in the -- in the specification 13 that -- 14 Q In the 1970s? 15 MR. LOCKE: Let her -- 16 THE WITNESS: And understand there was a 17 detection limit. 18 BY MR. TISI: 19 Q Honestly, that -- that's not my 20 question. Okay? 21 MR. LOCKE: Let her finish her answer, 22 and then you can ask -- 23 BY MR. TISI: 24 Q My question -- my question is this -- 25 this report assumes that asbestos had been</p>
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<p>1 for their statement. 2 Because the next paragraph, it says: 3 "Since the early '70s, the relevant industries 4 voluntarily eliminated asbestos from contamination 5 from talc products." 6 Do you see that? 7 A Yes. 8 Q Okay. So the assumption being that 9 there was no asbestos that had been eliminated, 10 correct? 11 A That's what it says. 12 Q Okay. What does the word "elimination" 13 mean to you? 14 MR. LOCKE: Objection. 15 THE WITNESS: Well, it was the '70s when 16 the asbestos issue was raised, and there was a lot 17 of work by the industry to develop a specification 18 that -- that said that there would be no 19 detectable asbestos. 20 BY MR. TISI: 21 Q Right. And so the -- but my question 22 is, what does the word "elimination" mean to you? 23 MR. LOCKE: Objection. 24 THE WITNESS: I think in this context it 25 means no detectable asbestos.</p>	<p>1 eliminated from talcum powder products since 1970. 2 True or not true? 3 MR. LOCKE: Objection. 4 THE WITNESS: I -- I think it's like 5 anything else, at some detection limit. I mean 6 every contaminant has a detection limit. So I 7 think that's implied. 8 BY MR. TISI: 9 Q Okay. And if asbestos -- let's assume 10 that you use the right test, right? I mean, you 11 could use -- you could use a -- if you used the 12 wrong test and you don't -- it may go undetected, 13 right? 14 A Well, as is true for any analysis. 15 Q Correct. Okay. 16 So my quest- -- my question is when you 17 make the -- the statement does not say -- because 18 everybody had an opportunity to look at this 19 before it went in. 20 When this statement is made to the FDA, 21 it says asbestos had been eliminated. True? 22 A Again, I think you can argue what 23 that -- what that word -- what is meant by that 24 word here. 25 Q Okay. Well, we can agree that if there</p>

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<p style="text-align: right;">Page 548</p> <p>1 was some asbestos in some -- in talcum powder</p> <p>2 products, that would provide a biologically</p> <p>3 plausible mechanism which would explain the</p> <p>4 increased risk, right?</p> <p>5 MR. LOCKE: Objection. Beyond the</p> <p>6 scope.</p> <p>7 BY MR. TISI:</p> <p>8 Q And that's what the FDA was asking</p> <p>9 about, right?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q Because on the May 8th -- let me</p> <p>13 rephrase the question.</p> <p>14 On the May 8th meeting with -- with you</p> <p>15 all, and you made the point several times, in</p> <p>16 addition to the epidemiology, the FDA wanted to</p> <p>17 know just how pure talcum powder products were.</p> <p>18 A They wanted to know -- they raised</p> <p>19 questions about sourcing and testing and how do</p> <p>20 you find the mines and -- and that type of stuff.</p> <p>21 Q Because they wanted to know how -- well,</p> <p>22 you knew the -- the reason why they were asking</p> <p>23 that question because they wanted to know what was</p> <p>24 in the bottle.</p> <p>25 A Yes. They were trying to understand --</p>	<p style="text-align: right;">Page 550</p> <p>1 MS. FRAZIER: Object to form.</p> <p>2 BY MR. TISI:</p> <p>3 Q Did you know that?</p> <p>4 A I'm not sure what that means.</p> <p>5 Q Meaning that they had talc samples from</p> <p>6 the mines, from the -- from -- from -- that the</p> <p>7 grade of talc that was used in the talcum powder</p> <p>8 products to actual physical bottles that were</p> <p>9 returned by consumers.</p> <p>10 Did you know that?</p> <p>11 A I guess no, not really.</p> <p>12 Q I mean, one of the things -- if the FDA</p> <p>13 was asking you questions about whether or not what</p> <p>14 was in the bottle might contain things other than</p> <p>15 pure talc, were you curious as the entity to say,</p> <p>16 Hey, guys, do you have any samples around we can</p> <p>17 test?</p> <p>18 A I mean, I --</p> <p>19 MR. LOCKE: Objection.</p> <p>20 THE WITNESS: -- think we had -- we had</p> <p>21 worked with FDA and companies looking at that</p> <p>22 question, if we're talking about asbestos back in</p> <p>23 the '70s.</p> <p>24 BY MR. TISI:</p> <p>25 Q Right. And you also made the point that</p>
<p style="text-align: right;">Page 549</p> <p>1 right.</p> <p>2 Q Right. This was not pharmaceutical</p> <p>3 grade talc. This was cosmetic talc, right?</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: I think it's basically the</p> <p>6 same as pharmaceutical grade talc, but yes.</p> <p>7 BY MR. TISI:</p> <p>8 Q But the point is there -- there are a</p> <p>9 lot of things -- so -- so what the FDA really</p> <p>10 wanted to drill down to here is -- I know you guys</p> <p>11 talked about, you know, talc as a molecule and</p> <p>12 whether or not it can cause ovarian cancer, and</p> <p>13 you addressed that issue, but are there other</p> <p>14 things in the bottle that might explain this</p> <p>15 increased risk? They asked you that question,</p> <p>16 right?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: And they asked us for</p> <p>19 follow-up information, which -- which we provided.</p> <p>20 BY MR. TISI:</p> <p>21 Q Now, one of the things we learned in</p> <p>22 this litigation is that these folks down here, the</p> <p>23 J&J and Imerys, had talc samples available to them</p> <p>24 for decades.</p> <p>25 MR. TISI: Objection.</p>	<p style="text-align: right;">Page 551</p> <p>1 some of those specifications were decades old,</p> <p>2 right? And one of the things that Dr. Bailey</p> <p>3 said, that they would be willing to look at -- at</p> <p>4 tightening up those specifications, right?</p> <p>5 MR. LOCKE: Objection.</p> <p>6 THE WITNESS: I think he did. I mean,</p> <p>7 there was always an openness -- obviously, FDA was</p> <p>8 welcome to do their own specification, but I don't</p> <p>9 think methodologies had substantially changed.</p> <p>10 BY MR. TISI:</p> <p>11 Q Well, do you know that?</p> <p>12 A Yes, actually, I think I could say I do.</p> <p>13 I think our specification is essentially the same</p> <p>14 as what the USP uses essentially. And I know like</p> <p>15 ASTM was looking at it, but they haven't changed</p> <p>16 anything or promulgated a new specification.</p> <p>17 Q So the question -- the question that I</p> <p>18 have here is, both the FDA and Dr. Bailey noted</p> <p>19 that the -- that the standards that were adopted</p> <p>20 in the 1970s were then decades old, correct?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Noted where? At the</p> <p>23 meeting?</p> <p>24 BY MR. TISI:</p> <p>25 Q At the meeting. It says here -- if you</p>

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<p style="text-align: right;">Page 552</p> <p>1 go back to the meeting notes, it says --</p> <p>2 MR. LOCKE: Can you tell us which</p> <p>3 exhibit you're referring to?</p> <p>4 MR. TISI: Exhibit No. 55.</p> <p>5 BY MR. TISI:</p> <p>6 Q It says -- if you go to page 2, it says:</p> <p>7 "Dr. Bailey mentioned that the Council published</p> <p>8 specifications for talc as well as analytical</p> <p>9 methodology for asbestos. These are the ones most</p> <p>10 often cited for the raw material. He mentioned</p> <p>11 these were developed almost 20 -- 20 years ago,</p> <p>12 and that they would need to be checked for</p> <p>13 verifications."</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q Okay. And so one of the things that the</p> <p>17 FDA and -- and the PCPC were talking about is, are</p> <p>18 our specifications for testing talc, are they</p> <p>19 outdated? Are they as stringent as they ought to</p> <p>20 be? Correct?</p> <p>21 MR. LOCKE: Object -- objection.</p> <p>22 THE WITNESS: That's what he's talking</p> <p>23 about here, yes, but he's certainly saying that we</p> <p>24 welcome FDA's --</p> <p>25 BY MR. TISI:</p>	<p style="text-align: right;">Page 554</p> <p>1 A -- and is used by USP.</p> <p>2 Q Did you go back and see whether or not</p> <p>3 there are other methods that would guarantee that</p> <p>4 asbestos had been eliminated -- well, let me</p> <p>5 rephrase the question for you.</p> <p>6 Is -- is it a -- would you agree with me</p> <p>7 that the goal here is to eliminate asbestos from</p> <p>8 cosmetic talc? You don't want any asbestos in</p> <p>9 cosmetic talc. Would you agree with that?</p> <p>10 A That's the ideal.</p> <p>11 Q That's the ideal.</p> <p>12 Particularly since this is a product</p> <p>13 that honestly there are other -- it's a cosmetic,</p> <p>14 and there are other alternatives out there, right?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: You don't need talc to</p> <p>17 live, yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q Right. And to the extent you do need it</p> <p>20 to live, there's corn starch, right?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: There's alternatives, yes.</p> <p>23 BY MR. TISI:</p> <p>24 Q Right. And so the question is, in light</p> <p>25 of that, you don't want any asbestos, none, zero.</p>
<p style="text-align: right;">Page 553</p> <p>1 Q Of course.</p> <p>2 A -- to weigh in, and --</p> <p>3 Q Right. But the -- but the question is,</p> <p>4 when these specifications were -- were developed</p> <p>5 in the 1970s, the epidemiology studies hadn't come</p> <p>6 out yet, right? They didn't come out until 1982.</p> <p>7 You made it clear that it was the early 1980s.</p> <p>8 A That's true, yes.</p> <p>9 Q Okay. And so now you had a new</p> <p>10 potential risk that was really raised by the</p> <p>11 epidemiology studies, and one of the questions</p> <p>12 that you had to answer is, are those a</p> <p>13 biologically plausible mechanism, right?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. TISI:</p> <p>17 Q Okay. And in light of that, did you</p> <p>18 ever go back and say, Do we need to tighten up our</p> <p>19 standards and to use a different measurement that</p> <p>20 would make sure that we had, using your terms in</p> <p>21 here, "eliminated asbestos"?</p> <p>22 A I guess I'm just aware that basically</p> <p>23 the methods -- methodology used is still what is</p> <p>24 used today --</p> <p>25 Q Right.</p>	<p style="text-align: right;">Page 555</p> <p>1 You want it eliminated. True?</p> <p>2 A You want it to be very low. My</p> <p>3 understanding is the methodologies that are used,</p> <p>4 it's actually gotten lower in detection limits,</p> <p>5 and we are using what -- again, the equivalent of</p> <p>6 a USP method.</p> <p>7 Q Okay. All right. Now, let's talk about</p> <p>8 other aspects of this report, if we could.</p> <p>9 First of all, can you -- I asked you</p> <p>10 whether or not -- on the asbestos issue, whether</p> <p>11 or not the company had ever gone back and -- the</p> <p>12 companies that were the primary people here had</p> <p>13 ever gone back and actually tested samples that it</p> <p>14 had in its possession that went back decades, and</p> <p>15 you indicated you didn't even know they had them,</p> <p>16 right?</p> <p>17 A Right.</p> <p>18 MR. LOCKE: Objection.</p> <p>19 BY MR. TISI:</p> <p>20 Q Were you able to produce to the FDA any</p> <p>21 testing records, any -- any literature, any</p> <p>22 outside audit, anything, that went back and looked</p> <p>23 at talc being tested to demonstrate the</p> <p>24 truthfulness of what Drs. Huncharek and Muscat</p> <p>25 assumed, that asbestos had been eliminated? Or</p>

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<p style="text-align: right;">Page 556</p> <p>1 did you just make the statement?</p> <p>2 A I mean there was a great deal of testing</p> <p>3 that went on in the early '70s --</p> <p>4 Q Right.</p> <p>5 A -- to show it was not detectable, and</p> <p>6 that's what the specification says.</p> <p>7 Q Got you. From the 1970s. Now you're</p> <p>8 meeting with them in -- in May of 2008. They're</p> <p>9 asking you about asbestos. Right? So now we're</p> <p>10 the '70s, '80s, '90s, 2000s, it's almost 30 years.</p> <p>11 Between the 1970s and the 2000s, did you</p> <p>12 come forward, either on your behalf or did any of</p> <p>13 these companies come forward and say, Look, we're</p> <p>14 going to show you proof that our talc from the</p> <p>15 1970s forward did not have asbestos in it, or was</p> <p>16 that statement just made?</p> <p>17 A I think it -- the basis of the statement</p> <p>18 was, again, the work that had done -- been done in</p> <p>19 the '70s to set up the specification. It was the</p> <p>20 discussions that followed with FDA to talk -- to</p> <p>21 answer the questions about sourcing and testing.</p> <p>22 Q Agreed.</p> <p>23 A I think if you're taking "elimination"</p> <p>24 to mean a literal zero, I can't think of any</p> <p>25 contaminant that anybody can say is a literal</p>	<p style="text-align: right;">Page 558</p> <p>1 cetera. I mean, the --</p> <p>2 BY MR. TISI:</p> <p>3 Q Well, the FDA on the translocation issue</p> <p>4 said that that's definitely biologically</p> <p>5 plausible.</p> <p>6 A They did say that.</p> <p>7 Q Okay. So let's --</p> <p>8 A I'm not sure what their basis was</p> <p>9 because they didn't reference, but they did say</p> <p>10 that.</p> <p>11 Q Well, but you didn't reference proof</p> <p>12 that there was -- okay. Let's -- so let's be fair</p> <p>13 here. Okay.</p> <p>14 You say the FDA didn't -- didn't</p> <p>15 reference the support for a translocation. Fine.</p> <p>16 What is your reference that in the</p> <p>17 1980s, 1990s and 2000s, there was no contaminants</p> <p>18 in talc, talcum powder products, that were</p> <p>19 potentially biologically plausible mechanisms that</p> <p>20 would explain what we all agree is a trend towards</p> <p>21 an increased risk seen in the epidemiology</p> <p>22 studies?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: I mean there was no</p> <p>25 evidence for talc itself. As I say, perfume</p>
<p style="text-align: right;">Page 557</p> <p>1 zero.</p> <p>2 Q So do you know -- did you take into</p> <p>3 account whether or not talcum -- talcum powder</p> <p>4 products have fragrances, right?</p> <p>5 A Yes.</p> <p>6 Q Did you look at the fragrances in there</p> <p>7 to see whether that provided a biologically</p> <p>8 plausible mechanism?</p> <p>9 MR. LOCKE: When you say "look" -- "did</p> <p>10 you look," are you referring --</p> <p>11 MR. TISI: PCPC.</p> <p>12 BY MR. TISI:</p> <p>13 Q Did PCPC, when it provided this report</p> <p>14 to the -- to the -- to the FDA talking about</p> <p>15 biologic plausibility, there's no way this</p> <p>16 happens, right? When you said that to the FDA,</p> <p>17 okay, did you consider whether or not what was in</p> <p>18 the bottle contained other things that might</p> <p>19 provide that mechanism?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: I mean, I -- I think when</p> <p>22 you're talking about fragrance, which we -- is</p> <p>23 part of a lot of products, I mean, we do not think</p> <p>24 of fragrances as being carcinogenic, not to</p> <p>25 mention the whole thing about translocation, et</p>	<p style="text-align: right;">Page 559</p> <p>1 fragrance is not regarded --</p> <p>2 BY MR. TISI:</p> <p>3 Q You don't look at it.</p> <p>4 A -- as a carcinogen.</p> <p>5 Q You don't look at it. Did you?</p> <p>6 A We --</p> <p>7 Q Has there been a lot of discussion</p> <p>8 about -- let me --</p> <p>9 A Fragrance in general. I mean it's used</p> <p>10 in body lotion, it's used in -- as fragrance.</p> <p>11 It's used in --</p> <p>12 Q Right, but it doesn't -- it doesn't --</p> <p>13 A It's not considered carcinogenic.</p> <p>14 Q -- it doesn't -- but is body lotion,</p> <p>15 does that come in contact with your ovaries,</p> <p>16 typically? Are there any epidemiology -- are</p> <p>17 there any epidemiologies that's --</p> <p>18 A The components of fragrance are not</p> <p>19 regarded as --</p> <p>20 Q Did you look?</p> <p>21 A Look at?</p> <p>22 Q Every component that was in the bottle,</p> <p>23 did you look at each one of them and see whether</p> <p>24 or not there was things that could be in that</p> <p>25 bottle that provided a biologically plausible --</p>

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<p style="text-align: right;">Page 560</p> <p>1 or did you look solely at pure talc?</p> <p>2 A I guess the -- the main thing I think of</p> <p>3 is fragrance, and certainly we've been concerned</p> <p>4 with fragrance and have an understanding of what</p> <p>5 fragrance materials are, and --</p> <p>6 Q Do you know whether or not -- did -- did</p> <p>7 you ask them whether it contains nickel and</p> <p>8 chromium and silica or any of those other --</p> <p>9 talcum powder comes from the ground, right?</p> <p>10 A Yes.</p> <p>11 Q Okay. And those are things that are</p> <p>12 not -- that are not desirable in talc either,</p> <p>13 right?</p> <p>14 A Correct.</p> <p>15 Q Okay. So my question is, your whole</p> <p>16 premise for this opposition for Citizen's</p> <p>17 Petition -- Dr. Epstein wanted a warning on talcum</p> <p>18 powder products, which is everything in the</p> <p>19 bottle. Right?</p> <p>20 A Yes.</p> <p>21 Q Your response focused on talc. Correct?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: Which makes up the vast</p> <p>24 majority of the product.</p> <p>25 BY MR. TISI:</p>	<p style="text-align: right;">Page 562</p> <p>1 A If somebody wanted to address our</p> <p>2 arguments and disagree with them, they could do</p> <p>3 so.</p> <p>4 Q Okay. So let's talk about -- let's just</p> <p>5 go here, because I think this will be -- and then</p> <p>6 we'll just break for lunch. I think it's lunch.</p> <p>7 Yeah, we'll break for lunch.</p> <p>8 If you go to page -- if you go to</p> <p>9 page 21 of the Introduction.</p> <p>10 A This is 21 --</p> <p>11 Q I'm sorry, 24 of 39 if you're looking at</p> <p>12 the --</p> <p>13 A 24 of 39, okay.</p> <p>14 Q So at the very last, it talks about</p> <p>15 experimental studies and clinical trials. Do you</p> <p>16 see that?</p> <p>17 It says: "In the contest of human</p> <p>18 studies, experimental design has come to represent</p> <p>19 the gold standard of cause and effect relationship</p> <p>20 as the randomized clinical trial."</p> <p>21 A Yes.</p> <p>22 Q Okay. First of all, would you agree</p> <p>23 with me -- I mean, you've done this for a long</p> <p>24 time -- you would agree with me that it would be</p> <p>25 both unfeasible and unethical to conduct a</p>
<p style="text-align: right;">Page 561</p> <p>1 Q The vast majority of the product but not</p> <p>2 all of the product. Correct?</p> <p>3 A I mean, we -- we have other lines of</p> <p>4 evidence, and our -- and -- and the arguments that</p> <p>5 we make are -- I mean, we're not alone in this.</p> <p>6 We're consistent that there is --</p> <p>7 Q I understand. But there are other</p> <p>8 people who think differently than you, right? You</p> <p>9 say you're not alone. There are other scientists</p> <p>10 who look at the evidence and think differently</p> <p>11 than you.</p> <p>12 A As -- as we've discussed.</p> <p>13 Q And they weren't in the room when you</p> <p>14 were discussing with the FDA, were they?</p> <p>15 A But, again, I -- I don't think we were</p> <p>16 even having --</p> <p>17 Q No, they were -- they were not in the</p> <p>18 room.</p> <p>19 MR. LOCKE: Let her finish the question.</p> <p>20 BY MR. TISI:</p> <p>21 Q They were not -- only you were in the</p> <p>22 room. And --</p> <p>23 A But we submitted this -- these are our</p> <p>24 arguments; they get posted on the website.</p> <p>25 Q Okay.</p>	<p style="text-align: right;">Page 563</p> <p>1 clinical trial where the hypothesis was, Let's</p> <p>2 give people talcum powder products and see whether</p> <p>3 it causes ovarian cancer.</p> <p>4 A Right. That's not how you do studies.</p> <p>5 Q You can't do it.</p> <p>6 A Right.</p> <p>7 Q So you can't -- so a clinical trial, if</p> <p>8 anyone were to kind of march on into court and</p> <p>9 say, You know, there were no clinical trials, you</p> <p>10 would expect to see clinical trials on this?</p> <p>11 A Correct. That's not how it's done.</p> <p>12 Q Right. So the next question is they</p> <p>13 have to rely on epidemiology research. Do you see</p> <p>14 that?</p> <p>15 A Yes.</p> <p>16 Q Okay. And they lay out a methodology</p> <p>17 here. It says: "An epidemiologist must observe</p> <p>18 observational methods to cause and effect</p> <p>19 relationship that preclude direct intervention on</p> <p>20 manipulation of study subjects."</p> <p>21 That's experiments, right?</p> <p>22 A Yes.</p> <p>23 Q All right. "Because of that fact,</p> <p>24 criteria for establishing cause and effect</p> <p>25 relationship are inherently different when</p>

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<p style="text-align: right;">Page 564</p> <p>1 utilizing epidemiologic methods versus 2 experimental ones." 3 Do you see that? 4 A Yes. 5 Q Okay. And so what they're saying is, 6 Look, you can't do a clinical trial because it's 7 unworkable, unethical. You just can't do it. So 8 you got to do it a different way. 9 A Yes. 10 Q Okay. And one of the ways that they do 11 it, they describe a -- a system or framework, 12 okay, and the framework is what we've called the 13 Bradford Hill criteria, and you've seen that 14 before? 15 A Yes. 16 Q And as somebody who's a scientist, 17 you're familiar with what that is? 18 A Yes. 19 Q Okay. And just to be clear, 20 Dr. Huncharek and Muscat make it clear, but I want 21 to make clear that from -- PCPC agrees with it as 22 well, these are criteria that are not really 23 criteria. They're -- they're considerations. 24 A They're -- right. Guidelines, I guess, 25 or -- right.</p>	<p style="text-align: right;">Page 566</p> <p>1 A I -- that's reasonable. 2 Q Okay. And that's not unusual in 3 science. Right? 4 A Correct. Scientists disagree. 5 Q I mean, for years there was a debate 6 about whether cigarette smoking causes cancer, 7 right? 8 MR. LOCKE: Objection. Beyond the 9 scope. 10 THE WITNESS: Yeah, before my time. I 11 think I've always known it, but yes. 12 BY MR. TISI: 13 Q Right. But you know that there was a 14 debate for decades on that question. 15 MR. LOCKE: Same objection. 16 THE WITNESS: I really don't. So... 17 BY MR. TISI: 18 Q You don't know that? 19 A No. 20 Q You must be much younger than me. 21 But you do know that -- that it is not 22 unusual for scientists to look at a question, 23 apply these factors, and come out with different 24 conclusions, correct? 25 A Yes.</p>
<p style="text-align: right;">Page 565</p> <p>1 Q Right. They're not things where you 2 kind of -- it's not like a menu where you check 3 off, Okay, we got this one, we got that one, we 4 got this one, right? 5 A You use it for overall, right, 6 assessment. 7 Q Right. And they make that point. They 8 say: "The Hill criteria, as they've become known, 9 are not simply a checklist of requirements that 10 must be met in order to determine a cause and 11 effect relationship." 12 And that's true, right? 13 A Yes. 14 Q Okay. And so these factors, and I think 15 they have nine of them here, are factors that are 16 considered, correct? 17 A Yes. 18 Q And -- and kind of what we were talking 19 about before that I think is really important to 20 kind of -- why this has been a debate is because 21 different scientists looking at the evidence have 22 come to different conclusions about these 23 different factors. 24 A Okay. 25 Q Is that true?</p>	<p style="text-align: right;">Page 567</p> <p>1 Q And so these are not criteria so much, 2 these Hill factors, as they are a framework of 3 considerations. 4 MR. LOCKE: Objection. Beyond the 5 scope. 6 BY MR. TISI: 7 Q True? 8 A "Framework" is what it says here. 9 Q And you agree with that? 10 A Yes. 11 Q They also say something here that I -- 12 that I want to see whether you agree with and you 13 agreed with at the time. 14 On page 26 of 29 -- well, one of the 15 things they say here is -- actually, let's go 16 back. 17 It says: "Overview. The possibility 18 that perineal talc exposure could be associated 19 with the development of ovarian cancer was 20 initially derived from a case controlled study 21 published in 1982." 22 Do you see that? 23 A Yes. 24 Q It's under "Overview." 25 A Yeah, now I see it.</p>

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<p style="text-align: right;">Page 568</p> <p>1 Q "Since that time a number of additional 2 reports have addressed this question with most 3 showing odds ratio between 1.0 and 2.0." Correct? 4 A Yes. 5 Q Okay. That's -- that's between -- if we 6 were to -- and for jurors who don't understand 7 odds ratios, that's basically showing anything 8 from a 1 percent increase to 100 percent increase. 9 A Correct. 10 Q Okay. 2.0 would be a doubling of the 11 risk. 12 A Correct. 13 Q And that's what they call -- they call 14 this a weak effect. Correct? 15 A Yes. 16 Q So just using the nomenclature that 17 Dr. Muscat and Huncharek used, they would 18 characterize something less than a hundred percent 19 doubling of the risk as being weak. 20 A Per an epidemiology study, yes. 21 Q Right. But in practical reality, if you 22 find something that doubles your risk, that is a 23 clinically -- if it is a true cause, that's 24 clinically significant, correct? 25 A If it --</p>	<p style="text-align: right;">Page 570</p> <p>1 Q Do you agree with it? 2 MR. LOCKE: Objection. Beyond the 3 scope. 4 BY MR. TISI: 5 Q On behalf of PCPC, is that something 6 that PCPC agreed with when they sent this to the 7 FDA? 8 MR. LOCKE: Objection. Beyond the 9 scope. 10 THE WITNESS: We -- yes. 11 BY MR. TISI: 12 Q Thank you. 13 Did PC -- they note down here that 14 obviously -- actually, let's skip that. 15 MR. LOCKE: Is this a good time for a 16 lunch break? 17 MR. TISI: Yeah, it's a good time to 18 break. 19 THE VIDEOGRAPHER: The time is 20 12:32 p.m., and we're going off the record. 21 (Lunch recess.) 22 THE VIDEOGRAPHER: The time is 1:12 23 p.m., and we are back on the record. 24 BY MR. TISI: 25 Q Dr. Loretz, we were talking about the</p>
<p style="text-align: right;">Page 569</p> <p>1 MR. LOCKE: Objection. 2 THE WITNESS: -- is a true cause. 3 MR. LOCKE: Beyond the scope. 4 BY MR. LOCKE: 5 Q If it is a true cause. All right. 6 So now the question is, if you go to 7 page 23, they make the point, and they go out of 8 their way to make it, actually, because they say: 9 "It is important to point out that although an 10 association is weak" -- 11 MR. LOCKE: Just wait -- wait one 12 second. You're referring to 23 at the top -- 13 MR. TISI: I'm sorry. 26 of 39, 14 correct. 15 BY MR. TISI: 16 Q "It is important" -- it says on the 17 first full paragraph: "It is important to point 18 out that although an association is weak" -- and 19 as they define "weak," that can include a doubling 20 of the risk, right? 21 A Up to. 22 Q Right. 23 -- "this does not rule out a causal 24 connection." Do you agree with that? 25 A That's what it says.</p>	<p style="text-align: right;">Page 571</p> <p>1 purity of talcum powder products that -- that's in 2 the bottle, and distinguishing it from talc in the 3 mine and et cetera, and before we took a break. 4 Do you remember that -- 5 A Yes. 6 Q -- session? 7 I have a couple more questions about 8 that and the document, but before I do, the focus 9 of the PCPC response was to focus on the 10 carcinogenic -- carcinogenic -- I'm sorry, let me 11 say it again. 12 The focus of the biologic plausibility 13 aspect of Dr. Muscat and Huncharek's response was 14 focused on two things. Number one, that talcum 15 powder products had been asbestos-free since 16 1970s, it had been eliminated. 17 Do you remember that? 18 A Yes. 19 Q Okay. Number two is that pure talc did 20 not -- there was no evidence that pure talc was 21 a -- had a mechanism that would lend itself to the 22 suggestion that it was a cause of ovarian cancer. 23 Correct? 24 A Right. 25 Q Right. So you were looking at asbestos,</p>

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<p style="text-align: right;">Page 572</p> <p>1 not there anymore; and talc, not a problem. 2 Right? 3 A Yes. 4 Q Okay. So -- but -- and we talked about 5 the question about whether or not talc really was 6 asbestos-free before the -- the break, and I'm not 7 going to go back into that again, but that was an 8 area of concern from the FDA's perspective, and 9 they raised it at the May meeting, May 2009. 10 A And -- and I'm sure -- we responded by 11 letting them know that the testing that had been 12 done and continued to be done. 13 Q Correct. Using -- 14 A And their own testing as well that they 15 did. 16 Q Using the 12 -- we'll talk about that in 17 a moment, but using the 20-year-old standards that 18 Dr. Bailey mentioned that they would be willing to 19 update. 20 A Which -- 21 MR. LOCKE: Objection. 22 BY MR. TISI: 23 Q Correct? 24 A Which they -- which, again, are not 25 substantially different from what is used today</p>	<p style="text-align: right;">Page 574</p> <p>1 attention that there are potentially other 2 components of talcum powder products, constituents 3 of talcum powder products, that need to be 4 considered when addressing the question as to 5 whether or not talcum powder products are a 6 potential cause of ovarian cancer? 7 A Are you talking about constituent 8 ingredients or are you talking about constituent 9 impurities? 10 Q Anything. Anything in the -- 11 A I mean -- 12 Q You know, honestly, and I'm trying to be 13 -- I'm trying to be as expansive as I can in this 14 question. 15 What I'm saying is, if I go to Walmart 16 and pull a bottle of talcum powder, Johnson's Baby 17 Powder off the shelf, whether they're impurities 18 or whether they're intended ingredients or 19 whatever, there are other constituents in there 20 that have to be considered in the algorithm of 21 whether or not talcum powder products cause 22 ovarian cancer. True? 23 A There are impurities that are covered by 24 the specification, for example. 25 Q Right. But -- but so my -- my question,</p>
<p style="text-align: right;">Page 573</p> <p>1 by, for example, USP. 2 Q Okay. So we discussed asbestos and 3 talc, and I started getting into the question, but 4 you know what's in the bottle, it's not only 5 asbestos and talc. Remember we started that 6 discussion before the break. 7 A Yes. 8 Q Okay. And in fact, that had been 9 brought to your attention long before this 10 petition was filed that talcum powder products may 11 contain things that might or might not be 12 carcinogens. 13 A Okay. 14 Q Well, is that true? 15 A I'm not sure what you're referring to. 16 Q Well, I'm asking you that before I -- 17 A I mean in the specific -- 18 Q -- show you a document -- 19 A In the specification we have some limits 20 set for a few other possible contaminants. 21 Q Well, had it ever been brought to your 22 attention that talcum -- you mentioned -- we 23 talked about fragrances, we talked about other 24 things. 25 Had it ever been brought to your</p>	<p style="text-align: right;">Page 575</p> <p>1 and I'm probably being inartful, so let me see if 2 I can phrase it. 3 We've previously discussed talcum powder 4 products as kind of this two-dimensional thing, 5 either it has asbestos or it doesn't have 6 asbestos. Right? So -- 7 A Okay. 8 Q So I'm -- I'm kind of moving off that 9 because it's not that simple, is it? 10 MR. LOCKE: Objection. 11 BY MR. TISI: 12 Q The question about whether or not there 13 is a biologically plausible mechanism by -- that 14 would explain the epidemiology studies which 15 showed, as Dr. Huncharek and Muscat point -- 16 pointed out, a risk between one and -- you know, 17 and a hundred percent, right? One to two, what 18 you say is called mild. The question should be 19 looked at comprehensively as to what is in the 20 bottle. 21 MR. LOCKE: Objection. 22 BY MR. TISI: 23 Q Right? 24 A Yes, I'm not aware of anything that -- 25 Q Well, did you look? I mean, the</p>

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<p>1 question is this -- this report that was sent to</p> <p>2 the FDA takes a very elemental view of the</p> <p>3 question. Prior to 1970, there was potential</p> <p>4 contamination with asbestos. It went out, and</p> <p>5 what's left is talc.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 BY MR. TISI:</p> <p>8 Q And talc doesn't cause cancer. That was</p> <p>9 the essence of their argument, correct?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: Well, no, I think there's</p> <p>12 more in their arguments -- I mean --</p> <p>13 BY MR. TISI:</p> <p>14 Q On the biologic plausibility issue, I</p> <p>15 mean, they talked about dose-response and all that</p> <p>16 stuff. But I'm talking about on the biologic</p> <p>17 plausibility, on the question of whether there is</p> <p>18 a -- an explanation that makes sense as to why</p> <p>19 there's this persistent increased risk, they</p> <p>20 looked basically at asbestos in talc.</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Yeah, I'm not sure what --</p> <p>23 what other -- what else you wanted to be -- them</p> <p>24 to address.</p> <p>25 BY MR. TISI:</p>	<p>1 throw it at you.</p> <p>2 BY MR. TISI:</p> <p>3 Q I'm really going to only ask you about</p> <p>4 the first page.</p> <p>5 A Mm-hmm.</p> <p>6 Q So just for the record, what this is,</p> <p>7 this is a document from IMA Europe. What is IMA?</p> <p>8 A Industrial Minerals Association.</p> <p>9 Q So it's another trade group like the</p> <p>10 PCPC?</p> <p>11 A Correct.</p> <p>12 Q Okay. It represents talc --</p> <p>13 A Mineral manufacturers, and talc is a</p> <p>14 subset of that.</p> <p>15 Q Okay. And it's to Dr. Muscat, correct?</p> <p>16 A Yes.</p> <p>17 Q Okay. Is this the same Dr. Muscat who</p> <p>18 wrote the report a couple of years later for you?</p> <p>19 A Yes.</p> <p>20 Q Robert Glenn at Crowell & Moring. R.</p> <p>21 Glenn.</p> <p>22 A I'm sure it is there. I don't see it.</p> <p>23 Q It's right after Joshua Muscat.</p> <p>24 A Yep. Yes.</p> <p>25 Q R. Glenn, Crowell & Moring, that's the</p>
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<p>1 Q Well, are there other things, either</p> <p>2 contaminants or intended ingredients, that should</p> <p>3 be factored into the equation that were not</p> <p>4 addressed by their -- had -- let me rephrase the</p> <p>5 question. And I'm sorry, I'm not being artful</p> <p>6 here.</p> <p>7 Are there other constituents within</p> <p>8 cosmetic talc that should be -- should have been</p> <p>9 considered on this biologically plausible</p> <p>10 mechanism issue that were not?</p> <p>11 A I -- I -- no, I'm not aware of --</p> <p>12 Q Okay. But no other constituents were in</p> <p>13 fact considered, right?</p> <p>14 A There's a specification that covers</p> <p>15 some.</p> <p>16 Q Okay. Were you ever made aware prior to</p> <p>17 this time that there were other potential</p> <p>18 constituents that had been classified as a</p> <p>19 carcinogen other than asbestos?</p> <p>20 A No.</p> <p>21 Q I'm going to show you what I would like</p> <p>22 to have marked as Exhibit No. 59.</p> <p>23 (Exhibit No. 59 was marked for</p> <p>24 identification.)</p> <p>25 MR. TISI: I'm sorry, didn't mean to</p>	<p>1 lawyers for --</p> <p>2 A Yes.</p> <p>3 Q -- they represent the lawyers for -- for</p> <p>4 Imerys.</p> <p>5 Linda Loretz is you?</p> <p>6 A Yes.</p> <p>7 Q Eric Turner, which is Luzenac, which is</p> <p>8 Imerys?</p> <p>9 A Yes.</p> <p>10 Q Jocelyn Ferret, which is Luzenac --</p> <p>11 A Yes.</p> <p>12 Q -- Imerys?</p> <p>13 So -- and cc'd was Steve Mann for --</p> <p>14 from J&J. You see that?</p> <p>15 A Yes.</p> <p>16 Q And it's entitled "IARC, Dr. Huncharek</p> <p>17 Comment." Do you see that?</p> <p>18 A Yes.</p> <p>19 Q Okay. And this is February 13th, 2006.</p> <p>20 This was during the IARC proceedings?</p> <p>21 A Okay. Yes.</p> <p>22 Q Is that right?</p> <p>23 A I would assume so, yes.</p> <p>24 Q And it's an e-mail from IMA North</p> <p>25 America to Joshua Muscat, who was the industry</p>

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<p style="text-align: right;">Page 580</p> <p>1 representative at IARC at the time.</p> <p>2 A Correct.</p> <p>3 Q Yes?</p> <p>4 A Yes.</p> <p>5 Q And it says: "What should be</p> <p>6 acknowledged is the difference between cosmetic</p> <p>7 talc grade, i.e., grade of talc, pure and</p> <p>8 extremely white, sold by talc producers at the</p> <p>9 gate of the mine" -- right?</p> <p>10 A Yes.</p> <p>11 Q -- "and cosmetic baby or body talc</p> <p>12 powder, i.e., loose powder manufactured by</p> <p>13 cosmetic manufacturers containing talc or corn</p> <p>14 starch, and also in the case of other minerals,</p> <p>15 kaolin, TiO₂, and all case additives such as</p> <p>16 perfumes and biocides, hexachlorophene in the</p> <p>17 past, a Category 3 IARC carcinogen" -- I won't</p> <p>18 even pronounce that -- imidazolidinyl urea" -- I</p> <p>19 don't know how to pronounce that -- "triclosan, et</p> <p>20 cetera. See documents sent by Jocelyn Ferret this</p> <p>21 morning."</p> <p>22 A Uh-huh.</p> <p>23 Q Okay. And the point that's being made</p> <p>24 here -- and, first of all, you got this. The</p> <p>25 point that's being made here is one of the things</p>	<p style="text-align: right;">Page 582</p> <p>1 When you filed your response to the</p> <p>2 Citizen's Petition, and addressed the issue of</p> <p>3 biologically plausible mechanisms, did you ask</p> <p>4 Dr. Muscat and Huncharek to look at each of the</p> <p>5 constituents in cosmetic talc sold in talcum</p> <p>6 powder products and see whether or not they</p> <p>7 individually or collectively might explain the</p> <p>8 increased risk?</p> <p>9 A I think the other ingredients that are</p> <p>10 used in talc are not carcinogenic.</p> <p>11 Q Well, did you -- what are the other</p> <p>12 talcs -- did you ask J&J to provide you with a</p> <p>13 list of -- list of products using talc?</p> <p>14 A List of ingredients used in talc?</p> <p>15 Q List of ingredients of talc.</p> <p>16 A No.</p> <p>17 Q Okay. So how do you know that none of</p> <p>18 them are carcinogenic?</p> <p>19 A We don't use carcinogens in cosmetics.</p> <p>20 Q You don't know what was in the talc that</p> <p>21 you were talking about with -- with the FDA, do</p> <p>22 you?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 BY MR. TISI:</p> <p>25 Q I mean -- I understand that</p>
<p style="text-align: right;">Page 581</p> <p>1 that really ought to be considered when you're</p> <p>2 talking about talcum powder products and the risk</p> <p>3 of ovarian cancer, you need to think about not</p> <p>4 only what comes out of the mine but what's in the</p> <p>5 bottle.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 BY MR. TISI:</p> <p>8 Q Right?</p> <p>9 A Okay.</p> <p>10 Q Well, I mean, I'm asking you whether you</p> <p>11 agree with that or not.</p> <p>12 A I can agree with that without thinking</p> <p>13 that this explains anything.</p> <p>14 Q Okay.</p> <p>15 A Yes.</p> <p>16 Q Okay.</p> <p>17 A I mean you think about -- when you think</p> <p>18 about safety of a product --</p> <p>19 Q Well, I'll take it and I'll put it aside</p> <p>20 then.</p> <p>21 A No, I'm just saying when you think about</p> <p>22 safety of a product, you think about everything in</p> <p>23 the product. So...</p> <p>24 Q Well, that's right. And -- and that's</p> <p>25 kind of where I'm going here.</p>	<p style="text-align: right;">Page 583</p> <p>1 aspirationally you don't want to have</p> <p>2 carcinogen -- carcinogens in the talc that you</p> <p>3 sell to women who may use them to dust themselves.</p> <p>4 I -- I understand that that might be an</p> <p>5 aspiration.</p> <p>6 But in light of the fact that this issue</p> <p>7 had been pending for decades, and now was firmly</p> <p>8 before the FDA in the Citizen's Petition, do you</p> <p>9 think that it might have been prudent to identify,</p> <p>10 just as was identified in this document I showed</p> <p>11 you, Exhibit No. 59, what all the constituents are</p> <p>12 in order to do a searching analysis of whether or</p> <p>13 not there was something in the talc that might be</p> <p>14 responsible for this increased risk?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: I mean, I guess, you know,</p> <p>17 I can look at this, and I recognize these</p> <p>18 ingredients, and --</p> <p>19 BY MR. TISI:</p> <p>20 Q Well, these are some of them and there</p> <p>21 may be others. I mean you -- what about did you</p> <p>22 know how much silica was in the -- if any, was in</p> <p>23 the talcum?</p> <p>24 A There's specifications.</p> <p>25 Q I understand the specifications. Apart</p>

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<p>1 from the specifications, do you know how much 2 silica there was? 3 A No. 4 Q Do you know how much magnesium there 5 was? 6 A I'm not sure that's regarded as a 7 carcinogen. 8 Q What about nickel? 9 A I know there was at one point, there was 10 a report and it was our understanding, because 11 this is what we were told, that it was bound up in 12 the talc and not free nickel. 13 Q Well, who told you that? 14 A I think it was J&J. 15 Q Okay. What about -- what about 16 silica -- is nickel a carcinogen? 17 A I don't believe it's recognized as an 18 ovarian carcinogen, but I'm -- I'm not an expert 19 on nickel cariogenicity. 20 Q Okay. If there -- if there was nickel, 21 it would be something that you would want to look 22 at, right? 23 A I think it depends. 24 MR. LOCKE: Objection. 25 THE WITNESS: I mean --</p>	<p>1 constituents, right? 2 A I believe that's true. 3 Q And they did not talk about any of the 4 fragrance or any of the other issues that are in 5 there, correct? 6 A For the same reason. 7 Q Okay. Talk about cobalt? 8 A No. 9 Q Arsenic? 10 A There is a specification for arsenic. 11 Q Right. But saying something has a 12 specification does not mean that it's absent, 13 correct? 14 A Right. I mean there's a specification 15 set, I believe it's 3 parts -- I believe it's 3 16 parts per billion. 17 Q Right. 18 A So it could be up to that. 19 Q So when you say something meets 20 specifications, the specifications are only as 21 good as the sensitivity and specificity of the 22 test that's being used. 23 A Well, the specifications are designed to 24 set a level that would be acceptable, i.e., safe, 25 and the method that goes with that should be</p>
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<p>1 BY MR. TISI: 2 Q Well, my -- my larger point here, 3 Doctor -- and, you know, I don't want to belabor 4 the issue -- is when you responded to the FDA, the 5 Citizen's Petition, there is nothing in this 6 response that addresses the potential of any 7 contaminants in the product, even ones that meet 8 specifications. Is there? 9 MR. LOCKE: Are you referring solely to 10 biological plausibility? 11 BY MR. TISI: 12 Q On the biologic plausibility issue, 13 there's no discussion at all, nickel, chromium, 14 silica, asbestos to the extent that's in it since 15 the 1970s, there's no discussion of that, is 16 there? 17 A Because those weren't recognized as 18 being risks. Just as I state some of these are 19 not -- 20 Q Okay. And that's -- it was not part of 21 Dr. Huncharek and -- and Muscat's analysis to the 22 FDA, right? 23 MR. LOCKE: Objection. 24 BY MR. TISI: 25 Q They did not mention those other</p>	<p>1 designed to -- 2 Q And did -- 3 A -- test at that level. 4 Q And did you -- because you were involved 5 with working with those standards, right, and 6 helping develop those standards, right? 7 A Oh, no, that was before my time. 8 Q Okay. Well, I didn't mean you. I meant 9 PCPC. 10 A PCPC, yeah, absolutely. 11 Q I was putting the PCPC hat on. 12 A Okay. Sorry. Got it. 13 Q All of those specifications were 14 developed before the epidemiological studies on 15 ovarian cancer, true? 16 A Developed but then updated, post. 17 Q I guess my question is, did any of 18 those -- were any of those specifications, to your 19 knowledge, analyzed by PCPC in the context of 20 looking for biologically plausible mechanisms for 21 ovarian cancer? 22 A I guess I'd go back to, I can see a 23 listing here that it just -- 24 Q I didn't ask you that question. You 25 told me that you could answer the question without</p>

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<p style="text-align: right;">Page 588</p> <p>1 looking at that document. 2 A Okay. 3 Q So I'm not looking at that document. 4 A Okay. 5 Q My question is, did you -- did PCPC in 6 the 2000s, while these epidemiological studies 7 were being published, analyze the specifications 8 for the elimination of these other constituents in 9 light of those epidemiology -- epidemiological 10 studies? 11 A We -- no, we were not aware of other 12 contaminants and/or ingredients that seemed to 13 offer a biological plausible reason for the cause 14 of ovarian cancer. 15 Q Well, cobalt might, right? Did you look 16 at the cobalt -- cobalt standards in connection 17 with ovarian cancer -- your standards? 18 A I was -- 19 MR. LOCKE: Objection. 20 THE WITNESS: I would say we had no 21 information that the cobalt contamination was a 22 problem, and I'm not aware that cobalt has been 23 implicated in ovarian cancer, although -- 24 BY MR. TISI: 25 Q Arsenic.</p>	<p style="text-align: right;">Page 590</p> <p>1 quite here yet. 2 A Okay. 3 Q So we'll put it up on the screen and 4 have it. 5 Dr. Epstein had previously filed a 6 Citizen's Petition before the FDA in the 1990s on 7 this issue, correct? 8 A Yes. 9 Q And at that time who did that petition 10 go to, do you know? 11 A John Bailey, I believe. 12 Q While he was at the FDA? 13 A I believe so, yes. 14 Q And did the FDA ever respond to that? 15 A Yes, they rejected that petition. 16 Q Well, didn't they -- didn't Dr. Bailey 17 write a letter to Mr. -- to Dr. Epstein that 18 said -- and we'll bring it up here. 19 MR. TISI: Can we bring it up, please? 20 MR. GOLOMB: I don't -- 21 MR. TISI: Well, we'll attach it as an 22 exhibit. No, that's it. Oh, is that it? No -- 23 yeah. 24 BY MR. TISI: 25 Q The last -- it's dated July 21st, 1995,</p>
<p style="text-align: right;">Page 589</p> <p>1 A -- I'm not an expert. 2 Q Arsenic. 3 A There's a specification for that. 4 Q Did you analyze that specification in 5 light of the -- the reported epidemiology results 6 of ovarian cancer in talc? 7 A I feel pretty comfortable saying that 8 the specification would -- would be okay, and I'm 9 not aware that arsenic has been implicated as an 10 ovarian carcinogen. 11 Q It didn't -- are they carcinogens? 12 Would it be something that would have been to be 13 looked at in light of the epidemiological studies? 14 MR. LOCKE: Objection. 15 THE WITNESS: I'm not sure that offers a 16 biologically plausible explanation. 17 BY MR. TISI: 18 Q So the fact that something -- okay. 19 All right. One other question. 20 (Counsel conferring.) 21 Q All right. Let's go to Exhibit No. -- 22 okay. 23 Now, I just want to go back to something 24 I discussed earlier today and see if I can -- this 25 was the document I was having printed. It's not</p>	<p style="text-align: right;">Page 591</p> <p>1 and that's Dr. Bailey who wrote that -- 2 MR. TISI: Can you make that -- 3 BY MR. TISI: 4 Q -- and his response was -- 5 MR. TISI: Go the second paragraph, 6 please. 7 MR. GOLOMB: Second one? 8 MR. TISI: Mm-hmm. 9 BY MR. TISI: 10 Q "The purpose of this is to advise you, 11 in accordance with 21 CFR 10.30(e)(2), that we 12 have not been able to reach a decision on your 13 petition within the first 180 days of the filing 14 of the petition because of limited availability of 15 resources and other agency priorities." 16 Is that accurate? 17 A Yes. 18 Q Okay. And this Citizen's Petition, the 19 one we've been talking about all day, wasn't 20 responded to for five years. Correct? 21 A Yes. 22 Q And that's the same division that 23 considered the first one, right? 24 A Well, I'm not sure when the response 25 came to the first one. I mean the 180 days and</p>

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<p>1 that is -- I think it's pretty typical for 2 petitions that they, I believe, have some 3 obligation to respond, but that response can be to 4 say that we're not -- we're not done yet. 5 (Exhibit No. 60 was subsequently 6 marked for identification.) 7 BY MR. TISI: 8 Q Okay. I'm going to mark it as 9 Exhibit No. 60 when we get it. 10 So let me ask you this: I'm going to go 11 through each year, and I'm going to ask you, you 12 responded to the FDA questions that they asked 13 you, correct, at this May 9th -- 14 A Yes. 15 Q -- meeting? 16 Did PCPC in 2009, other than this 17 meeting, have any communications directly or 18 indirectly with FDA relating to asbestos in talc 19 other than responding to the questions? 20 A You can refresh my memory if there's 21 any. I -- I can't recall any. 22 Q This is -- you can't recall any. 23 2009, did PCPC have any direct or 24 indirect communications with FDA regarding the 25 issue of talc and ovarian cancer?</p>	<p>1 questions. 2 A Okay. 3 Q The first question is going to be 4 communications with the FDA on talc and ovarian 5 cancer association or risk. 6 And the second question is going to be 7 on specifications for talc, and particularly with 8 regard to asbestos. Okay? 9 So the first question, in 2010, do you 10 recall any question or any communications with FDA 11 regarding the issue of ovarian cancer and talc? 12 A I don't recall any, no. 13 Q Any communications with the FDA on any 14 specifications for issues relating to asbestos or 15 levels of asbestos in talc? 16 A Not that I recall. 17 Q Okay. 2011, same two questions. If you 18 want, I'll separate them out. 19 A I'm just trying to make sure I'm not 20 forgetting something. I don't recall, no. 21 Q 2012? 22 A And again, the question was on 23 asbestos -- 24 Q It was on the association between 25 ovarian cancer and talc or the asbestos levels or</p>
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<p>1 MR. LOCKE: Other than what we've 2 discussed? 3 MR. TISI: Other than what we -- I'm 4 sorry, I meant to say 2010. I'm sorry. 5 THE WITNESS: That's what I was confused 6 on. I was trying to -- 7 BY MR. TISI: 8 Q Yeah, I'm sorry. 9 A -- decide if you -- 10 Q Yeah. No, no, it was -- 11 A Okay. Got it. 12 Q It was a mistake. 13 A Okay. 14 Q Just to be clear, let me -- I'm going to 15 go through each year -- 16 A Okay. 17 Q -- and I want to find out what your 18 communications were in each year. 19 A That's what I thought you were doing. 20 Okay. 21 Q So 2010. 22 A I want to be careful not to forget 23 something. So the question was anything to do 24 with -- 25 Q Let's -- I want to ask you two separate</p>	<p>1 specifications for talc. 2 A And did you say meetings? 3 Q Any communications directly or 4 indirectly. 5 A I guess -- 6 Q I guess what I'm trying to do in kind of 7 a summary fashion is to ask you about any 8 communications. These are the ones that I've been 9 able to find. I found -- you know, I can go 10 through your answers -- 11 A Mm-hmm. 12 Q -- to the FDA questions and do that. 13 A Mm-hmm. 14 Q Other than that. 15 A Yeah, and I'm just trying to be careful 16 so I'm being -- being accurate. 17 Q Yeah. 18 A And I can say I'm not aware of any. I 19 know in 2000 -- when FDA, for example, did their 20 sampling plan, could someone in meeting with the 21 FDA on something else asked a question, how's it 22 going, you know, that's possible. But a meeting 23 specific to that or something -- some deep 24 discussions or work on a specification, not that 25 I'm aware of.</p>

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<p>1 Q Okay. Let me see if I can ask it this</p> <p>2 way, since we got through 2011.</p> <p>3 When is the next time, if ever, PCPC</p> <p>4 directly or indirectly spoke to the FDA about talc</p> <p>5 and ovarian cancer?</p> <p>6 A I'm just trying to think if I'm</p> <p>7 forgetting anything.</p> <p>8 I'm -- I'm not recalling. Again, there</p> <p>9 was the -- FDA did the assessment on the asbestos.</p> <p>10 There could have been conversations. I --</p> <p>11 Q Anything that you -- that you know of as</p> <p>12 you sit here right now, anything to -- and are</p> <p>13 prepared to testify to as a -- as a representative</p> <p>14 of PCPC?</p> <p>15 A Not that I can think of.</p> <p>16 Q Okay. When is the next time you talked</p> <p>17 about asbestos levels in talcum powder products or</p> <p>18 asbestos testing in talcum powder products, if</p> <p>19 ever?</p> <p>20 MR. LOCKE: With the FDA?</p> <p>21 MR. TISI: With the FDA.</p> <p>22 THE WITNESS: Oh, we're aware that FDA</p> <p>23 did their study, and we're aware, I mean, that our</p> <p>24 members test in a -- on an ongoing basis.</p> <p>25 BY MR. TISI:</p>	<p>1 discuss with your members whether you had a more</p> <p>2 fulsome survey that could be conducted either of</p> <p>3 currently marketed products or of, you know,</p> <p>4 samples that had been stored over time?</p> <p>5 A No, I think our answers -- when we</p> <p>6 answered FDA to their questions about testing, et</p> <p>7 cetera, I think -- I mean, that addressed it kind</p> <p>8 of in an ongoing way. So --</p> <p>9 Q Okay. You basically said, We tested it</p> <p>10 as we always did?</p> <p>11 A Yeah.</p> <p>12 Q So, as I understand it, from -- do you</p> <p>13 know who Susan Nicholson is from J&J?</p> <p>14 A Nettesheim?</p> <p>15 Q No, Nicholson.</p> <p>16 A Oh, no.</p> <p>17 Q I understand that J&J had a meeting with</p> <p>18 FDA in 2018. Do you know anything about that?</p> <p>19 A That would be this year.</p> <p>20 Q That would be this year.</p> <p>21 A No.</p> <p>22 Q Do you know of any communications that</p> <p>23 the company had with FDA about the lawsuits that</p> <p>24 have been pending and verdicts that have been</p> <p>25 obtained against the manufacturers of talc --</p>
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<p>1 Q Well, okay, let's -- since you raised</p> <p>2 that issue, FDA did a sampling of -- of certain</p> <p>3 products bought in the Washington, D.C. area, I</p> <p>4 think they said five out of nine, they -- there</p> <p>5 was -- that wasn't a study, was it? That wasn't a</p> <p>6 study, correct?</p> <p>7 A They -- they --</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: Yeah, that's not exactly</p> <p>10 what they did. They did -- I think they did from</p> <p>11 suppliers, and then they did 30-some products off</p> <p>12 the shelf.</p> <p>13 BY MR. TISI:</p> <p>14 Q Right. But they -- the FDA admitted</p> <p>15 that that was not a --</p> <p>16 A The FDA said it's not exhaustive.</p> <p>17 Q It's not -- they -- they went further</p> <p>18 than that. They said it was not -- they could not</p> <p>19 guarantee that this was a true sampling of talcum</p> <p>20 powder products out there, correct?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: They said it was not --</p> <p>23 not a final answer, yes.</p> <p>24 BY MR. TISI:</p> <p>25 Q Right. And in that context, did you</p>	<p>1 A I do not.</p> <p>2 Q -- and talc products?</p> <p>3 MR. LOCKE: Well, just to clarify, when</p> <p>4 you say "the company," you're talking about J&J?</p> <p>5 MR. TISI: J&J.</p> <p>6 THE WITNESS: No.</p> <p>7 BY MR. TISI:</p> <p>8 Q Or -- or Imerys.</p> <p>9 Are you aware of any communications</p> <p>10 about the lawsuits that have --</p> <p>11 A That those companies have had with FDA?</p> <p>12 Q Yes.</p> <p>13 A No.</p> <p>14 Q Okay. So other -- the last meeting that</p> <p>15 you know of that you had that was formally or</p> <p>16 informally with the FDA on the issues of talcum</p> <p>17 powder products and ovarian cancer was in May of</p> <p>18 2008?</p> <p>19 MR. LOCKE: '9.</p> <p>20 THE WITNESS: '9.</p> <p>21 BY MR. TISI:</p> <p>22 Q '9. I'm doing what -- what Dr. Bailey</p> <p>23 did. Sorry.</p> <p>24 Just to be clear, the last time that</p> <p>25 you're aware of that PCPC had any direct contact</p>

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<p>1 with the FDA, either directly or indirectly, was</p> <p>2 the meeting in May of 2009, and any follow-up to</p> <p>3 that meeting that was requested by the FDA?</p> <p>4 A Something specific to that topic. As I</p> <p>5 say, it doesn't mean there weren't -- you know,</p> <p>6 when FDA unveiled their results about talc</p> <p>7 testing, it doesn't mean somebody didn't ask a</p> <p>8 question or whatever, but --</p> <p>9 Q Well, do you know of any questions they</p> <p>10 might have asked?</p> <p>11 A No, I don't.</p> <p>12 Q Okay. Okay.</p> <p>13 A But, I mean, we have FDA, for example,</p> <p>14 presents at kind of our meetings sometimes. I</p> <p>15 could see a question being asked. I just --</p> <p>16 Q But you don't know of any.</p> <p>17 A No, I do not.</p> <p>18 Q All right. So let's go to the second</p> <p>19 question, the second area that I said we would</p> <p>20 cover, which is studies and consultants.</p> <p>21 A Okay.</p> <p>22 Q I'm kind of done with the Citizens</p> <p>23 Petitions --</p> <p>24 A Okay.</p> <p>25 Q -- and contacts with the FDA issue.</p>	<p>1 A Correct.</p> <p>2 Q Now, if go to page 2, there's a section</p> <p>3 called "Manuscript Reviews." Do you see that?</p> <p>4 A Okay. Yes.</p> <p>5 Q And the second bullet point says: "The</p> <p>6 meta-analysis manuscript -- manuscript prepared by</p> <p>7 Dr. Gross, "and it has a number, "was discussed.</p> <p>8 It was agreed on the scientific content of the</p> <p>9 manuscript was good, but the format lacked</p> <p>10 clarity," and it goes on and on. Do you see that?</p> <p>11 A Yes.</p> <p>12 Q Okay. Are you familiar with the study</p> <p>13 by Dr. Gross?</p> <p>14 A I saw the manuscript in my preparation</p> <p>15 for this deposition.</p> <p>16 Q Now, I'm going to show you there was a</p> <p>17 published article by Gross and Berg. Have you</p> <p>18 seen that?</p> <p>19 A I think that sounds familiar.</p> <p>20 Q May I see --</p> <p>21 (Counsel conferring.)</p> <p>22 BY MR. TISI:</p> <p>23 Q Okay. I'm going to mark this as Exhibit</p> <p>24 No. 61, and I'm actually going to give you 62,</p> <p>25 which is I think the manuscript that you just may</p>
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<p>1 A Okay.</p> <p>2 Q Let's start in the 1990s. I'm going to</p> <p>3 go back to Exhibit No. 47, which is the notes from</p> <p>4 April 12th, 1994.</p> <p>5 A Okay.</p> <p>6 Q And that's the task force document.</p> <p>7 A Yes.</p> <p>8 Q And just -- you may have mentioned this</p> <p>9 the last time in your deposition, and I'm sorry,</p> <p>10 I'm trying not to retread old ground, but can you</p> <p>11 tell us what the task force was?</p> <p>12 A So this is the Talc Interested Party</p> <p>13 Task Force, so these are specifically people who</p> <p>14 have an interest in talc and are willing to pay</p> <p>15 for projects as well when required. And these are</p> <p>16 just the member companies, again, with an interest</p> <p>17 in the topic.</p> <p>18 Q Okay. And listed on this document are</p> <p>19 Johnson & Johnson, Luzenac, American Westminster,</p> <p>20 is that --</p> <p>21 A I don't know.</p> <p>22 Q I don't know that either.</p> <p>23 -- Procter & Gamble Company, Cosmair,</p> <p>24 Colgate Palmolive, Helene Curtis, and then CTFA,</p> <p>25 which is PCPC.</p>	<p>1 have referred to.</p> <p>2 (Exhibit Nos. 61 and 62 were</p> <p>3 marked for identification.)</p> <p>4 MR. TISI: Here is your copy. And here</p> <p>5 is 62.</p> <p>6 BY MR. TISI:</p> <p>7 Q Now, 61 is the published article,</p> <p>8 correct?</p> <p>9 A Yes.</p> <p>10 Q And 62 is the internal report, right?</p> <p>11 A Oh, I'm sorry. I haven't seen 62 yet.</p> <p>12 Yes.</p> <p>13 Q So one is titled -- the memorandum is</p> <p>14 entitled "Meta-Analysis." Right?</p> <p>15 A Yes.</p> <p>16 Q Okay. And you all paid, at least in</p> <p>17 part, for this, right?</p> <p>18 A I believe so, yes.</p> <p>19 Q And if you go to the back, the draft</p> <p>20 paper, the one that was not published, and you go</p> <p>21 to page 33, it says: "Financial support for this</p> <p>22 study was provided in part by the Cosmetic</p> <p>23 Toiletry and Fragrance Association."</p> <p>24 A Yes.</p> <p>25 Q Now --</p>

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<p>1 MR. GOLOMB: Wait, Chris, the document</p> <p>2 is not up yet.</p> <p>3 BY MR. TISI:</p> <p>4 Q If you go to page --</p> <p>5 MR. GOLOMB: That's the wrong document.</p> <p>6 MR. TISI: 62, yeah.</p> <p>7 Yeah, that's right, go to the very end.</p> <p>8 It's the Bates 188.</p> <p>9 BY MR. TISI:</p> <p>10 Q And the Acknowledgment section</p> <p>11 acknowledges what I think you told us in your</p> <p>12 interrogatories: "The financial support for this</p> <p>13 study is provided in part by the Cosmetic,</p> <p>14 Toiletry and Fragrance Association, correct?</p> <p>15 A Yes.</p> <p>16 Q Okay. Now, the report actually went</p> <p>17 through peer review, right, and actually was</p> <p>18 published?</p> <p>19 A It looks that way, yes.</p> <p>20 Q Yeah. And when it was published, did</p> <p>21 you ask -- did PCPC ask that their name be taken</p> <p>22 off the acknowledgment? Because they're not on</p> <p>23 the acknowledgment of the published paper.</p> <p>24 A I see that J&J is.</p> <p>25 I -- I don't know what happened on that</p>	<p>1 A As we've discussed, yes.</p> <p>2 Q And that reflects -- and if you go back</p> <p>3 to my chart here, my -- my timeline, this reflects</p> <p>4 the concerns that talcum powder products may cause</p> <p>5 ovarian cancer, and there was an active debate</p> <p>6 among scientists. That was the concept we talked</p> <p>7 about earlier.</p> <p>8 A Yes.</p> <p>9 Q If you go to page --</p> <p>10 MR. TISI: I'm sorry?</p> <p>11 (Counsel conferring.)</p> <p>12 Q Okay. Let's go back to -- if you go to</p> <p>13 page 192 of the study, the Discussion section.</p> <p>14 A I'm sorry. Which one?</p> <p>15 MR. LOCKE: 192.</p> <p>16 THE WITNESS: I know. Which document?</p> <p>17 BY MR. TISI:</p> <p>18 Q The actual published study.</p> <p>19 A Okay.</p> <p>20 Q The authors -- and these are people who</p> <p>21 were hired by -- paid for by you all, right?</p> <p>22 A Again, I'm a little confused because it</p> <p>23 says J&J.</p> <p>24 Q Okay. But J&J was actually the -- you</p> <p>25 know --</p>
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<p>1 funding.</p> <p>2 Q Well, let's go to the published paper</p> <p>3 and see what the published paper says. Okay?</p> <p>4 A Mm-hmm.</p> <p>5 Q The one that actually went through peer</p> <p>6 review. Right?</p> <p>7 A Yes.</p> <p>8 Q Okay. First of all, and this -- so that</p> <p>9 the jury understands, this is dated 1995.</p> <p>10 A Okay.</p> <p>11 Q This is some 10 -- 13 years before</p> <p>12 the -- before the Citizen's Petition.</p> <p>13 A Okay.</p> <p>14 Q Right?</p> <p>15 A Yes.</p> <p>16 Q And so this is -- it says: "The concern</p> <p>17 that use of talc or talc" -- this is the first</p> <p>18 sentence of the abstract -- "the concern that use</p> <p>19 of talc or talc-containing substances in the</p> <p>20 perineal region of women may subject them to an</p> <p>21 increased risk of ovarian cancer has become an</p> <p>22 important issue in the study of ovarian cancer."</p> <p>23 Is that -- did I read that correct?</p> <p>24 A That's what it says, yes.</p> <p>25 Q And that's true, right?</p>	<p>1 A Certainly part of, right, industry.</p> <p>2 Q Right. So the discussion says:</p> <p>3 "Existing evidence linking talc exposure to an</p> <p>4 increased risk of ovarian cancer cannot be viewed</p> <p>5 as scientifically conclusive based upon the</p> <p>6 available epidemiological studies." Right?</p> <p>7 A Mm-hmm. Yes.</p> <p>8 Q Is it your view that the evidence must</p> <p>9 be conclusive before women are told of the</p> <p>10 potential risk in a cosmetic product?</p> <p>11 MR. LOCKE: Objection. Beyond the scope</p> <p>12 and to form.</p> <p>13 BY MR. TISI:</p> <p>14 Q You may answer the question. Must the</p> <p>15 evidence be conclusive before women are told of</p> <p>16 the potential risk?</p> <p>17 MR. LOCKE: Same objection.</p> <p>18 THE WITNESS: Yeah, I -- I --</p> <p>19 BY MR. TISI:</p> <p>20 Q You know that the standard is that -- we</p> <p>21 talked about this early on in the deposition --</p> <p>22 the standard is warnings should be added when</p> <p>23 there may be a risk, correct?</p> <p>24 MR. LOCKE: Objection. Beyond the scope</p> <p>25 and form.</p>

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<p style="text-align: right;">Page 608</p> <p>1 BY MR. TISI:</p> <p>2 Q You're told -- you know that, right?</p> <p>3 MR. LOCKE: Same objection.</p> <p>4 BY MR. TISI:</p> <p>5 Q You actually publish -- PCPC publishes a</p> <p>6 labeling book for its members, correct?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: The labeling book deals</p> <p>9 with current labeling requirements.</p> <p>10 BY MR. TISI:</p> <p>11 Q Right. And you know that warnings</p> <p>12 should be added when there may be a risk, correct?</p> <p>13 MR. LOCKE: Objection. Beyond the scope</p> <p>14 and to form.</p> <p>15 THE WITNESS: Yeah, that seems like a</p> <p>16 legal labeling issue that's not anything --</p> <p>17 BY MR. TISI:</p> <p>18 Q But you were responding to a Citizen's</p> <p>19 Petition regarding labeling, right? You were</p> <p>20 responding to that?</p> <p>21 A We were responding to the science piece</p> <p>22 of --</p> <p>23 Q Right. And I asked you what the</p> <p>24 standard was because doctor -- Dr. Epstein was</p> <p>25 asking for a label change. Right?</p>	<p style="text-align: right;">Page 610</p> <p>1 says: "However, all the meta-analysis arrive at a</p> <p>2 relative risk rate of 1 with a 95 percent</p> <p>3 confidence interval excluding the null."</p> <p>4 That's basically saying that all the</p> <p>5 meta-analysis done as of that time showed an</p> <p>6 increased risk, correct?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: Well, that's the</p> <p>9 meta-analysis. That's not the individual studies.</p> <p>10 BY MR. TISI:</p> <p>11 Q The purpose of a meta-analysis is to</p> <p>12 combine studies to increase the power of a study</p> <p>13 to determine a risk, right?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: I mean I'm not an</p> <p>16 epidemiologist, but I would say, yes, that's their</p> <p>17 basic purpose.</p> <p>18 BY MR. TISI:</p> <p>19 Q And the last page on page 193, and this</p> <p>20 is of a 1995 article funded by you all.</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Oh, yeah, it's -- I'm not</p> <p>23 sure what happened here. The authors changed, the</p> <p>24 things changed, and the -- the acknowledgments</p> <p>25 changed. So I -- I don't want to say this was</p>
<p style="text-align: right;">Page 609</p> <p>1 MR. LOCKE: You're asking her what you</p> <p>2 asked her?</p> <p>3 BY MR. TISI:</p> <p>4 Q No, I -- you know that Dr. Epstein was</p> <p>5 asking for a label change to add a warning about a</p> <p>6 potential risk, right?</p> <p>7 A I know that that's what he was asking</p> <p>8 for, correct.</p> <p>9 Q And you responded and opposed that,</p> <p>10 correct?</p> <p>11 MR. LOCKE: Objection.</p> <p>12 THE WITNESS: Based on the science.</p> <p>13 BY MR. TISI:</p> <p>14 Q Right. And I asked you before, did you</p> <p>15 know the standard, correct?</p> <p>16 A And I think I said I didn't, that that</p> <p>17 was a legal --</p> <p>18 Q Okay. And so you responded to the</p> <p>19 petition not knowing what the standard was.</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: We responded by offering</p> <p>22 scientific -- expert epidemiologists' opinion on</p> <p>23 what the epidemiology shows.</p> <p>24 BY MR. TISI:</p> <p>25 Q Now, at the last sentence here, Dr. Berg</p>	<p style="text-align: right;">Page 611</p> <p>1 funded by PCPC. That's not what it says. And</p> <p>2 there's definitely a change in authorship here, so</p> <p>3 things changed.</p> <p>4 BY MR. TISI:</p> <p>5 Q The last sentence says: "The -- thus,</p> <p>6 the body of knowledge found in the medical</p> <p>7 literature does not unequivocally support the</p> <p>8 hypothesis that talc use puts women at an</p> <p>9 increased risk of ovarian cancer. However, the</p> <p>10 results of this meta-analysis do suggest the</p> <p>11 possibility of an increased ovarian cancer due to</p> <p>12 peritoneal -- perineal talc use."</p> <p>13 Do you see that?</p> <p>14 A Yes.</p> <p>15 Q And these were the same authors at least</p> <p>16 that were the people that you all hired to do a</p> <p>17 meta-analysis, correct?</p> <p>18 A Well, I think we hired Dr. Gross, but I</p> <p>19 don't think we hired Dr. Berg, so that's why I'm</p> <p>20 saying I'm not sure.</p> <p>21 Q And Dr. Berg -- Dr. Berg, I will</p> <p>22 represent to you, was -- was a doctoral student of</p> <p>23 Dr. Gross. And that's made clear in other</p> <p>24 documents.</p> <p>25 A Okay.</p>

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<p style="text-align: right;">Page 612</p> <p>1 Q He was basically given coauthorship, but</p> <p>2 it was really Dr. Gross.</p> <p>3 So can you say -- these appear to be the</p> <p>4 same. This one is March 17, 1994. This</p> <p>5 meta-analysis -- published meta-analysis is 1995.</p> <p>6 One says it's sponsored by J&J, the other one says</p> <p>7 CTFA.</p> <p>8 Do you agree that this is likely the</p> <p>9 same study?</p> <p>10 A I think it looks like it's related, yes.</p> <p>11 Q Okay. So this is one study that you</p> <p>12 authored -- that you were involved with.</p> <p>13 Let's go through another one.</p> <p>14 MR. LOCKE: Objection.</p> <p>15 BY MR. TISI:</p> <p>16 Q Let's go back to the task force</p> <p>17 document. 1994.</p> <p>18 The last page, number 4 under the --</p> <p>19 this is under a heading entitled "Future Research</p> <p>20 Needs." Do you see that?</p> <p>21 A The last page?</p> <p>22 Q If you go to page --</p> <p>23 A I see "Future Research Needs."</p> <p>24 Q Right. And if you go to the last page,</p> <p>25 number 4.</p>	<p style="text-align: right;">Page 614</p> <p>1 that?</p> <p>2 A Yes.</p> <p>3 Q And at this time frame, as in others,</p> <p>4 this was an important issue, right? That's why</p> <p>5 you guys were meeting.</p> <p>6 A That's what we were talking about, yes.</p> <p>7 Q And other than the Berg article which we</p> <p>8 just discussed, are you aware of any industry-</p> <p>9 sponsored epidemiological study or meta-analysis</p> <p>10 that actually looked at the question specifically</p> <p>11 of whether ovarian cancer and talc were related?</p> <p>12 A Industry study, no.</p> <p>13 Q Given the importance of the issue, don't</p> <p>14 you find that a little odd?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 BY MR. TISI:</p> <p>17 Q It was discussed, right, should we do a</p> <p>18 study?</p> <p>19 A Right. I don't know what the follow-up</p> <p>20 was, but, I mean, I guess the question is, is it</p> <p>21 going to make a difference and is it going to be</p> <p>22 criticized for being an industry study?</p> <p>23 Q Well, if the industry study found what</p> <p>24 everyone else said, then everyone would be on the</p> <p>25 same table, right? They would all -- everyone</p>
<p style="text-align: right;">Page 613</p> <p>1 A Okay.</p> <p>2 Q Okay. Do you see that?</p> <p>3 A Yes.</p> <p>4 Q It says -- I don't know who MNordhauser</p> <p>5 is, but that seems to be a person, right?</p> <p>6 A I think it's Mary Ann Nordhauser.</p> <p>7 Q Okay. She pointed out: "The importance</p> <p>8 of considering other research directions in which</p> <p>9 the task force should be involved. Ms. Nordhauser</p> <p>10 suggested the task force consider sponsoring</p> <p>11 further epidemiological studies. It was noted</p> <p>12 that Dr. Ernst Wynder discussed an outline of such</p> <p>13 a research proposal at the IS RTP symposium. Mike</p> <p>14 Chudkowski agreed to discuss the developments of</p> <p>15 such a proposal with Dr. Wynder."</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q Okay. And was it important during the</p> <p>19 1990s for the CTFA and the members of the talc</p> <p>20 task force to do research into the area that we've</p> <p>21 been discussing, ovarian cancer and talc?</p> <p>22 A I guess I think it was discussed to see</p> <p>23 if -- you know --</p> <p>24 Q Well, she says: "The importance of</p> <p>25 considering research directions." Do you see</p>	<p style="text-align: right;">Page 615</p> <p>1 would all agree.</p> <p>2 MR. LOCKE: Objection.</p> <p>3 BY MR. TISI:</p> <p>4 Q Well, let me ask you this: Are you</p> <p>5 aware that Dr. Wynder did in fact propose a study?</p> <p>6 A I'm not aware.</p> <p>7 Q Do you know at the time you mentioned --</p> <p>8 now doctor -- who is Dr. Wynder?</p> <p>9 A I don't know.</p> <p>10 Q Do you know Dr. Wynder was with the</p> <p>11 American Health Foundation?</p> <p>12 A I guess I do now.</p> <p>13 Q You know the American Health Foundation</p> <p>14 was the same foundation where Dr. Muscat worked?</p> <p>15 A Yes.</p> <p>16 Q Do you know that Dr. Muscat proposed an</p> <p>17 epidemiology study to J&J to follow up exactly on</p> <p>18 this issue in 1994, 1995?</p> <p>19 A No, I don't know that. I mean, I</p> <p>20 believe that. I just don't know that.</p> <p>21 (Exhibit No. 63 was marked for</p> <p>22 identification.)</p> <p>23 BY MR. TISI:</p> <p>24 Q I'm going to show you Exhibit No. 63.</p> <p>25 Now, I'll represent to you, because I</p>

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<p style="text-align: right;">Page 616</p> <p>1 don't like to misrepresent things, that the --</p> <p>2 that this is a composite exhibit. Okay. If you</p> <p>3 notice the top is a grant application, but if you</p> <p>4 notice the Bates numbers are -- don't coincide</p> <p>5 directly with the attachment.</p> <p>6 We discussed it with Dr. Muscat the</p> <p>7 other day, so there is -- this was a -- he used a</p> <p>8 grant application to Johnson & Johnson, but the</p> <p>9 actual proposal is attached.</p> <p>10 A Okay.</p> <p>11 Q Okay?</p> <p>12 A Yes.</p> <p>13 Q And you see that this is a proposal from</p> <p>14 1994?</p> <p>15 A Yes.</p> <p>16 Q This would have been within six months</p> <p>17 of the CTFA Talc Interested Party Task Force --</p> <p>18 MR. DUFFY: Counsel, can you confirm</p> <p>19 that what's in these exhibits is a composite</p> <p>20 exhibit --</p> <p>21 MR. TISI: Absolutely. Absolutely. It</p> <p>22 is two documents. The one is the actual</p> <p>23 application itself.</p> <p>24 MS. FRAZIER: Are there any other copies</p> <p>25 of that since --</p>	<p style="text-align: right;">Page 618</p> <p>1 MR. TISI: Okay. I thought it was -- I</p> <p>2 thought it was December 1994, but okay.</p> <p>3 So -- and there's a -- there's actually</p> <p>4 a letter sent to J&J listing this out, and I won't</p> <p>5 go into detail about it.</p> <p>6 BY MR. TISI:</p> <p>7 Q But my question is this appears to be a</p> <p>8 follow-up --</p> <p>9 MR. TISI: Do you have a copy of that</p> <p>10 letter?</p> <p>11 Okay. Could we take a break for one</p> <p>12 minute while we get a copy of the letter?</p> <p>13 THE VIDEOGRAPHER: The time is 2:06 p.m.</p> <p>14 We're going off the record.</p> <p>15 (Recess.)</p> <p>16 THE VIDEOGRAPHER: The time is 2:16 p.m.</p> <p>17 We're back on the record.</p> <p>18 BY MR. TISI:</p> <p>19 Q Doctor, I don't want to belabor the</p> <p>20 point because I know we've been going a little</p> <p>21 while, and I've got to turn my time over to other</p> <p>22 people.</p> <p>23 But do you know whether or not J&J --</p> <p>24 first of all, the study that you have in front of</p> <p>25 you is a case controlled study.</p>
<p style="text-align: right;">Page 617</p> <p>1 MR. TISI: Yeah. Yeah.</p> <p>2 MR. DUFFY: This one kind of came apart.</p> <p>3 MR. TISI: Okay. It was testified to by</p> <p>4 Dr. Muscat the other day, so they refer to the</p> <p>5 same thing.</p> <p>6 The first -- and just to be clear for</p> <p>7 the record, the top exhibit is a grant application</p> <p>8 entitled "Talcum Powder Use in Ovarian Cancer,</p> <p>9 Joshua Muscat, Research Scientist," on behalf of</p> <p>10 the American Health Foundation.</p> <p>11 There is actually a letter that goes</p> <p>12 along with it as well, and attached is that actual</p> <p>13 proposal for case controlled study of talcum</p> <p>14 powder use and ovarian cancer.</p> <p>15 MR. DUFFY: Thank you.</p> <p>16 MR. TISI: You're welcome.</p> <p>17 BY MR. TISI:</p> <p>18 Q And I'll represent to you that both of</p> <p>19 these documents are dated 2000 and -- actually,</p> <p>20 1994.</p> <p>21 A Okay.</p> <p>22 MR. LOCKE: Well, one says, not the --</p> <p>23 January 31st, 1995.</p> <p>24 MR. TISI: Okay. The second one?</p> <p>25 MR. LOCKE: Yes.</p>	<p style="text-align: right;">Page 619</p> <p>1 A Okay.</p> <p>2 Q Do you -- well, do you see it? It's</p> <p>3 entitled "Proposal for a Case Controlled Study of</p> <p>4 Talcum Powder Use in Ovarian Cancer."</p> <p>5 MR. LOCKE: If you go back to page 78 at</p> <p>6 the bottom there.</p> <p>7 THE WITNESS: This one? Yep. Okay. I</p> <p>8 see it, yes.</p> <p>9 BY MR. TISI:</p> <p>10 Q So there's a study -- this is actually a</p> <p>11 study proposal, okay?</p> <p>12 A Yes.</p> <p>13 Q So just so we have the time frame down,</p> <p>14 the -- in 1994, you all had a meeting. There was</p> <p>15 a suggestion that J&J follow up and see whether or</p> <p>16 not an additional study could be done by</p> <p>17 Dr. Wynder's group. This is Dr. Wynder's group,</p> <p>18 the American Health Foundation. They proposed a</p> <p>19 study, and the study was a case controlled study.</p> <p>20 Does that appear to be true?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: That appears to be true.</p> <p>23 BY MR. TISI:</p> <p>24 Q Did -- now, the study, if you go back</p> <p>25 one page, is about a \$400,000 study.</p>

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<p style="text-align: right;">Page 620</p> <p>1 A That's what it says, yes.</p> <p>2 Q All right. Now, I have a document</p> <p>3 here -- first of all, had you ever -- before</p> <p>4 coming here today, had you heard about this study</p> <p>5 or know anything about it?</p> <p>6 A I don't believe so, no.</p> <p>7 Q Okay. I'm going to provide you with a</p> <p>8 document, page -- it's Exhibit No. 15, and it says</p> <p>9 "Draft Never Sent," but I'm curious as to whether</p> <p>10 or not there was any other documents related to</p> <p>11 that.</p> <p>12 (Exhibit No. 64 was marked for</p> <p>13 identification.)</p> <p>14 MR. LOCKE: This is also marked 63.</p> <p>15 MR. TISI: Right -- oh, I'm sorry. Let</p> <p>16 me -- what number are we at now?</p> <p>17 MR. LOCKE: 64.</p> <p>18 MR. TISI: See without my -- so what's</p> <p>19 the next one we're at?</p> <p>20 MR. LOCKE: 64 is the one we're -- that</p> <p>21 one should -- would be.</p> <p>22 MR. TISI: Thank you, Tom.</p> <p>23 BY MR. TISI:</p> <p>24 Q Let me see if this somehow raises a --</p> <p>25 the specter to you that perhaps maybe this was</p>	<p style="text-align: right;">Page 622</p> <p>1 many possible confounders which had previously</p> <p>2 been ignored. The study will take two and a half</p> <p>3 years to complete and cost nearly \$400,000."</p> <p>4 Did I read that so far?</p> <p>5 A Yes.</p> <p>6 Q "We at J&J have reviewed the proposal</p> <p>7 and believe the study could help clarify the many</p> <p>8 obvious shortcomings in the previously reported</p> <p>9 studies. For as long as I've been on the Talc</p> <p>10 Interested Party Task Force, we have discussed</p> <p>11 ways to improve our understanding of cosmetic talc</p> <p>12 use. I think the task force should sponsor the</p> <p>13 study as an industry initiative. Would you please</p> <p>14 poll the members about the idea and put this</p> <p>15 subject on our upcoming task force meeting and</p> <p>16 agenda?"</p> <p>17 Do you see that?</p> <p>18 A Yes.</p> <p>19 Q And I read that correctly?</p> <p>20 A Yes.</p> <p>21 Q Okay. Do you know whether or not J&J</p> <p>22 ever brought to the attention of the -- the CTFA</p> <p>23 the \$400,000 well-designed, carefully designed</p> <p>24 study that Dr. Muscat drafted when he was with the</p> <p>25 American Health Foundation?</p>
<p style="text-align: right;">Page 621</p> <p>1 discussed with Dr. Gettings. First of all, this</p> <p>2 is --</p> <p>3 MR. GOLOMB: Could we just get that</p> <p>4 document up on the screen?</p> <p>5 MR. TISI: Yeah, May 5th -- it's 139.</p> <p>6 BY MR. TISI:</p> <p>7 Q And it says -- it's a -- it's a letter,</p> <p>8 and it says "Draft Never Sent" on top. So I don't</p> <p>9 want to -- I don't know whether you got it or you</p> <p>10 didn't get it or you got another version of it or</p> <p>11 whatever. I haven't seen anything in the records</p> <p>12 relating to this, but --</p> <p>13 A I haven't --</p> <p>14 Q -- I don't know whether or not anything</p> <p>15 in your -- in your travels you may have found</p> <p>16 something.</p> <p>17 It says, Dr. Gettings: "Dear Steve:</p> <p>18 This provides you with a copy of a talc proposal</p> <p>19 prepared by Dr. Joshua Muscat and Dr. Ernst Wynder</p> <p>20 of the American Health Foundation. They are</p> <p>21 proposing a new more definitive epidemiology study</p> <p>22 examining the hypothesized link between hygienic</p> <p>23 use of cosmetic talcum powder and the incidence of</p> <p>24 ovarian cancer. It is a very carefully designed</p> <p>25 study with special attention paid to -- paid to</p>	<p style="text-align: right;">Page 623</p> <p>1 MS. FRAZIER: Object to form.</p> <p>2 THE WITNESS: I'm not aware. I don't</p> <p>3 believe I've seen this or seen discussion of it.</p> <p>4 BY MR. TISI:</p> <p>5 Q Is this the kind of study that the -- I</p> <p>6 mean, we talked about the fact that the CTFA and</p> <p>7 PCPC was very interested in the science</p> <p>8 surrounding talc. Right?</p> <p>9 A Yes.</p> <p>10 Q And have been interested for decades,</p> <p>11 right?</p> <p>12 A Yes.</p> <p>13 Q Do you have any reason to believe that</p> <p>14 such a study had been brought to the attention of</p> <p>15 the CFTA that such a study would not have been</p> <p>16 funded and done?</p> <p>17 A I really don't know. I mean, I think</p> <p>18 you really would have to -- yeah, I can't say</p> <p>19 without having had that experience of bringing it</p> <p>20 and asking who was willing to do the funding.</p> <p>21 Q Has anybody -- has J&J ever proposed a</p> <p>22 study, in all of your experience with them, or</p> <p>23 proposed an action that CTFA decided it was not</p> <p>24 going to do, that you can think of?</p> <p>25 A We -- we -- I mean just overall, not</p>

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<p>1 outside of the area of talc, I mean sometimes we 2 talk about studies and people either decide to do 3 them or not. 4 Q Okay. So -- but this study that was 5 proposed by Dr. Muscat to help understand the 6 issue was never sent to the members of the task 7 force to the best of your knowledge? 8 A I'm -- I'm not aware of it. I don't 9 believe I've seen this before. 10 Q Do you know why -- I mean in all this 11 time, decades have gone by, and the -- the 12 company -- the companies involved in the task 13 force have never done an epidemiology study to 14 study perineal talc and ovarian cancer? 15 A I guess I can't answer that. I mean, I 16 guess the question could be, you know, would it 17 make a difference and would an industry study be 18 taken without it being assumed that it wasn't as 19 good as another study? I don't know. But I don't 20 know. 21 Q Okay. Well, that doesn't stop you all 22 from doing studies, does it? 23 A Well, it doesn't, except that it -- I 24 mean it -- it becomes an issue. 25 Q So you could always hire an outside</p>	<p>1 identification.) 2 BY MR. TISI: 3 Q This is a 2003 study. And I only have 4 one copy, but since I know it by heart, I'm not 5 going to need it. 6 Do you know whether or not this is a 7 study -- I assume you saw it. You're familiar 8 with that study, it's a 2003 study by 9 Dr. Huncharek? 10 A I -- yes. 11 Q Is that a study that -- were you aware 12 of that study before it was published? 13 A No. 14 Q Okay. Was -- was PCPC in any way made 15 aware of the study before it was published? 16 A No. 17 Q Okay. Did PCPC -- we discussed the two 18 papers from Dr. Huncharek and Muscat that was in 19 the letter from -- the e-mail from Mr. Glenn. 20 A Yes. 21 Q I can attach those two studies here. 22 MR. TISI: Do you have those two 23 studies? 24 (Counsel conferring.) 25 MR. TISI: 51 or 52, if you can get</p>
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<p>1 group to do it, right, and not have any role in 2 the -- in the design of the study, no role in the 3 editing of the study, no role -- no approve -- 4 approval or non-approval of the text, right? I 5 mean there are times when that's done, right? 6 MR. LOCKE: Objection. 7 THE WITNESS: I guess I can't think of 8 anywhere we've done a study like that. 9 BY MR. TISI: 10 Q Right. Because you always want to know 11 what the authors are saying about a study you fund 12 before you agree that it gets published, right? 13 MR. LOCKE: Objection. 14 THE WITNESS: I mean, in general, yes, 15 if we're funding a study, we want to -- 16 BY MR. TISI: 17 Q So you're unaware of this particular 18 study and why it was and was not done. 19 A Yes. I don't believe I've seen it. 20 Q Now, I'm going to show you a study that 21 was done by Dr. Huncharek, Exhibit No. -- 22 MR. TISI: Which exhibit are we on? 23 MR. LOCKE: 65. 24 MR. TISI: Do you have a sticky? 25 (Exhibit No. 65 was marked for</p>	<p>1 those. 2 BY MR. TISI: 3 Q Now, other than being aware of them 4 before they were published, was PCPC involved in 5 any way with the review of these articles? 6 MR. LOCKE: Objection. 7 THE WITNESS: They were not. 8 BY MR. TISI: 9 Q Do you know who Brooke Mossman is? 10 A I have heard the name. She's at 11 Vermont, and I know it, yes. 12 Q University at Vermont? 13 A I think so. 14 Q Do you know that she was involved in 15 funded studies relating to the cellular response 16 to -- to both asbestos and talc? 17 A That sounds familiar, yes. 18 Q Do you know that those studies were 19 funded by IMA North America? 20 A No. I mean, I -- I have probably run 21 across that. I know they were not funded by us, 22 but that -- 23 Q Okay. And that was my question is, do 24 you know -- were you involved in any discussions 25 about funding any studies by Dr. Mossman?</p>

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<p>1 A He may have been asked about it. I'm</p> <p>2 not sure, but we did not fund any.</p> <p>3 Q There was a study that Dr. Mossman</p> <p>4 proposed. Are you familiar with the Shukla paper?</p> <p>5 A Not by that name.</p> <p>6 Q It's a Mossman -- it's a published</p> <p>7 Mossman study.</p> <p>8 A Okay.</p> <p>9 Q Are you aware that Dr. Mossman had</p> <p>10 proposed a follow-up study that industry declined</p> <p>11 to fund?</p> <p>12 A That sounds familiar.</p> <p>13 Q Have you ever understood why a</p> <p>14 company -- or what do you understand about that</p> <p>15 study?</p> <p>16 A I -- I am hard-pressed to remember what</p> <p>17 it was about.</p> <p>18 Q Do you understand that she wanted to</p> <p>19 look at different kinds of talc and how it reacted</p> <p>20 to ovarian cancer cells?</p> <p>21 A I -- I just don't remember.</p> <p>22 Q Do you know whether or not -- why PCPC</p> <p>23 decided not to fund that study?</p> <p>24 A If that's as I remember, because that's</p> <p>25 how I remembered, is there was one study, and we</p>	<p>1 (Exhibit No. 66 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. TISI:</p> <p>4 Q First of all, if you go to page 10, it</p> <p>5 says -- actually, hold on a second.</p> <p>6 Okay. On page 12, it says: "Around</p> <p>7 April 1997, CTFA sought the assistance of</p> <p>8 consultant epidemiologists to evaluate a study on</p> <p>9 powder exposure and perineal cancer."</p> <p>10 A I'm sorry, page 12?</p> <p>11 Q Page 12.</p> <p>12 A Oh, second paragraph. Okay.</p> <p>13 Q Do you see that?</p> <p>14 A Yes.</p> <p>15 Q Do you know what study that refers to?</p> <p>16 A April '97. I should know.</p> <p>17 Q The only study I found is the Cooke</p> <p>18 study. Does that sound familiar?</p> <p>19 A Oh, yeah. I think so.</p> <p>20 Q Would that have been the Cooke study?</p> <p>21 A I couldn't tell you off the top what</p> <p>22 year the Cooke study was, but it would be --</p> <p>23 because I'm not thinking of any other event, I</p> <p>24 think it would be a single study that --</p> <p>25 Q I'm going to show you the Cooke study,</p>
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<p>1 ask our people and -- if they want to fund, and</p> <p>2 basically it's -- you know, either they do or they</p> <p>3 don't, and we would not necessarily know, and nor</p> <p>4 would -- nor would the reason be the same among</p> <p>5 companies.</p> <p>6 Q Did you ever discuss with either J&J or</p> <p>7 Imerys why they were not interested in funding</p> <p>8 that follow-up study by Dr. Mossman?</p> <p>9 MS. FRAZIER: Object to form.</p> <p>10 THE WITNESS: Not that I recall.</p> <p>11 BY MR. TISI:</p> <p>12 Q Now, let's go to -- I'd like to go to</p> <p>13 the answers to interrogatories that were produced,</p> <p>14 and I'm on my last page here.</p> <p>15 Your counsel provided to us a set of --</p> <p>16 a second set of supplemental interrogatories on</p> <p>17 Friday.</p> <p>18 A Okay.</p> <p>19 Q Have you seen them?</p> <p>20 A I believe so, yes.</p> <p>21 MR. LOCKE: Actually, I think it was</p> <p>22 Thursday, but --</p> <p>23 MR. TISI: Okay. It doesn't matter to</p> <p>24 me. I worked all weekend anyway.</p> <p>25 MR. LOCKE: Okay. Thank you.</p>	<p>1 and it's Exhibit No. 67.</p> <p>2 (Exhibit No. 67 was marked for</p> <p>3 identification.)</p> <p>4 BY MR. TISI:</p> <p>5 Q And ask you whether you believe that</p> <p>6 that's the case that you asked a consultant to</p> <p>7 look at.</p> <p>8 A So again, I think this was before I was</p> <p>9 at CTFA, which is why I don't know.</p> <p>10 Q Right.</p> <p>11 A But I know we had a couple of individual</p> <p>12 studies assessed, so timingwise, I guess this</p> <p>13 makes sense. So I would --</p> <p>14 Q This is my only opportunity --</p> <p>15 A That seems plausible.</p> <p>16 Q It's my only opportunity to really ask</p> <p>17 questions of PCPC about this.</p> <p>18 Do you believe that this is the study?</p> <p>19 A I mean, if I -- if I saw that there was</p> <p>20 a -- if we -- yes. I'm going to go yes.</p> <p>21 Q Okay.</p> <p>22 MR. LOCKE: Just for the record, we do</p> <p>23 reference a document there that might shed light</p> <p>24 on it in the interrogatory response.</p> <p>25 MR. TISI: Yeah, and it's not -- it</p>

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<p>1 wasn't helpful, candidly, but I can go back and 2 figure it out. 3 BY MR. TISI: 4 Q It sought the assistance of consulting 5 epidemiologists to evaluate the article. Do you 6 know which epidemiologists they were? 7 A I don't. 8 Q Do you know whether it was Dr. Muscat? 9 A I don't think so. 10 Q Do you know that Dr. Muscat wrote a 11 letter to the editor regarding the Cooke paper? 12 A No, I don't -- I don't think I knew 13 that. I -- I wasn't aware -- again, I wasn't 14 here, so -- 15 Q I understand. I'm asking you with your 16 hat on as PCPC. 17 A No, totally agree. I just -- I'm just 18 saying I wasn't aware that we used Dr. Muscat 19 before 2000. 20 Q Okay. I'm going to show you -- I'm 21 going to put this -- and we will get an exhibit. 22 But here is a letter to the editor on 23 the -- 24 MR. TISI: Can you put it up? 25 (Counsel conferring.)</p>	<p>1 MR. LOCKE: We will see. Okay. 2 BY MR. TISI: 3 Q Okay. One last couple of questions, and 4 then I'm going to kind of be done with it. 5 I asked you whether or not the industry 6 or CTFA or individually the industry members had 7 done an epidemiology study studying ovarian cancer 8 and talc, and you had indicated that you were 9 unaware of any, correct? 10 A That's correct. 11 Q Are you aware of any study in which the 12 company did any toxicology studies on animals and 13 ovarian cancer? 14 A The -- through CTFA, the -- it was the 15 monkey study was -- I guess two monkey studies or 16 one -- one pre-study, one study on translocation. 17 Q Okay. But none looking at cellular -- 18 whether or not talc or any talc constituent causes 19 cellular changes in ovarian cancer cells in 20 animals? 21 A I can't think of anything. 22 Q Okay. And that would be something that 23 certainly could be done, right? 24 A I mean something -- 25 MR. LOCKE: Objection.</p>
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<p>1 BY MR. TISI: 2 Q I'm going to put it up on the screen and 3 we'll just have to substitute it. 4 And this will be Exhibit No. 68. 5 (Exhibit No. 68 was marked for 6 identification.) 7 BY MR. TISI: 8 Q And here is a letter to the editor in 9 1997 from Dr. Muscat and Dr. Wynder from the 10 American Health Foundation. 11 Do you see that on the screen? 12 A Sort of, yes. 13 Q I'm not going to ask you to comment on 14 it. 15 A Right. 16 Q I'm asking you do you believe that -- 17 that -- I'm trying to understand. 18 Would Dr. Muscat and the American Health 19 Foundation have been the epidemiologists with whom 20 you likely consulted to critique the Cooke paper? 21 A I guess I just would have to say that's 22 possible. 23 MR. TISI: Okay. Counsel, I'm going to 24 ask you, on behalf of PCPC, if you could clarify 25 that for us, if you don't mind.</p>	<p>1 THE WITNESS: Yeah, something could be 2 done, but you'd have to -- I mean, one would need 3 to think about that further as to what could be 4 done, if it would make sense. If it would, you 5 know, really shed any light on -- 6 BY MR. TISI: 7 Q Well, I mean, without being facetious, 8 you all had about 40 years to think about it. 9 The question is, did you ever talk with 10 amongst the members and say, Maybe we ought to do 11 an animal study seeing whether or not talcum 12 powder products or any constituent of those 13 products cause cellular changes in ovaries of any 14 particular animal? 15 MR. LOCKE: Objection. 16 THE WITNESS: I -- I'm not sure there 17 wasn't something done. Not by us, but -- no, we 18 didn't -- we didn't do anything. 19 BY MR. TISI: 20 Q Okay. Any -- there was a discussion in 21 one of the -- in the e-mail that Mr. Glenn sent 22 you in 2005 asking whether or not CTFA would do a 23 dose-response study, because that was one of the 24 Bradford Hill criteria that you all thought didn't 25 -- didn't support causation, and asked whether you</p>

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<p style="text-align: right;">Page 636</p> <p>1 would fund a study by Rothman or something that 2 could be published on dose-response. 3 Did you all discuss that? 4 MR. LOCKE: Objection. 5 THE WITNESS: We had Dr. Rothman's and 6 Dr. Samet's and Dr. Pastides' paper. 7 BY MR. TISI: 8 Q From 2000? 9 A His assessment. And we -- right, he -- 10 he did not propose reasonable terms that -- for us 11 to take that forward. 12 Q Okay. Could you explain that a little 13 more, because I'm not really sure -- 14 A He wanted to charge such an incredible 15 amount, it was far out of the ballpark of being 16 reasonable. 17 Q Okay. Well, I -- I'm still not 18 understanding. Did he propose to do a follow-up 19 study to look at dose-response? 20 A No. No, it wasn't -- it wasn't that. 21 He was proposing to turn his -- the submission 22 that he was -- coauthored into a publication. 23 Q Okay. And how much did he charge -- did 24 he want to charge? 25 A \$100,000.</p>	<p style="text-align: right;">Page 638</p> <p>1 Q That -- that report that was done by 2 Dr. Rothman and Pastides and Samet was never 3 submitted to a journal for peer review, was it? 4 MR. LOCKE: Just to clarify, you're 5 talking about the 2000 NTP? 6 MR. TISI: Correct. 7 THE WITNESS: Correct. It was submitted 8 to NTP. 9 BY MR. TISI: 10 Q But it was never submitted for 11 publication in any peer-reviewed journal. 12 A That's correct. 13 Q Okay. And you declined to support 14 that -- that submission for cost reasons, correct? 15 A Only because it was very unreasonable. 16 Q Okay. Did you ever propose to 17 anybody -- did anyone ever propose to PCPC or 18 anybody else that a dose-response study actually 19 be undertaken? 20 A I think that was talked about, and I 21 think there was concern that it was something that 22 had been done by somebody else, and should we be 23 doing that. And again, when I say the cost was 24 high, it was just well out of the bounds of what 25 you would expect. I mean it wasn't even close.</p>
<p style="text-align: right;">Page 637</p> <p>1 Q And you all decided thanks but no 2 thanks? 3 A That's not a reasonable number. 4 Q Okay. And then in 2005, Luzenac came 5 back to you and said, you know, We really think 6 it's important to publish a study on dose- 7 response. Would you consider it? 8 And that was -- we could pull it out, 9 but that was the e-mail we talked about Huncharek 10 and Muscat. Do you remember that? 11 A Yes. 12 Q Did you go back to the well and say, you 13 know, Maybe you ought to publish it and do a 14 published study on dose-response? 15 MR. LOCKE: Objection. 16 THE WITNESS: No. Again, we had the 17 assessment done, but we -- no, we did not go 18 forward to have that made into a publication. 19 BY MR. TISI: 20 Q That publication was never subject to 21 peer review, was it? 22 A No. I mean it was -- it was a -- 23 Q I'm sorry. Let me rephrase the 24 question. 25 A Yeah.</p>	<p style="text-align: right;">Page 639</p> <p>1 Q Well, let me ask you this, and I will 2 represent to you -- and I don't have a copy of it 3 right here. Maybe I do. 4 This is Exhibit No. 69. 5 (Exhibit No. 69 was marked for 6 identification.) 7 BY MR. TISI: 8 Q I will represent to you in 2009, 9 Drs. Huncharek and Muscat proposed all kinds of 10 studies that could be done to further elucidate -- 11 elucidate the issue. Smoking and ovarian risks, 12 hysterectomy and tubal ligation, completion and 13 publication of Rothman's dose-response analysis, 14 et cetera, and then they subsequently propose 15 their own dose-response study. 16 Do you know whether any of those were 17 brought -- any of these proposals were brought to 18 the PCPC? 19 A I'm not aware that they were. 20 Q Okay. Do you currently have any studies 21 that you are -- have either considered -- well, 22 let me ask you this: Other than the ones we've 23 discussed, can you think of any study that was 24 proposed to the PCPC or by the PCPC relating to 25 the -- any issue relating to ovarian cancer and</p>

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<p>1 talc?</p> <p>2 A I'm sorry, what was the first part of</p> <p>3 your question?</p> <p>4 Q Do you know of any study that was either</p> <p>5 proposed to the PCPC or by the PCPC relating to</p> <p>6 any issue regarding talcum powder products and</p> <p>7 ovarian cancer?</p> <p>8 A I mean, I guess the monkey study, and</p> <p>9 then --</p> <p>10 Q No, that wasn't done. That was</p> <p>11 proposed.</p> <p>12 A Oh, that wasn't done.</p> <p>13 Q Yeah.</p> <p>14 A I think not a -- maybe not a hard core</p> <p>15 -- well, the ones you've talked about, I mean the</p> <p>16 Mossman. But again, I'm not sure there's any that</p> <p>17 came to proposal. I mean, I guess it's the things</p> <p>18 we're talking about now, right?</p> <p>19 Q Well, I'm asking if there's anything</p> <p>20 else.</p> <p>21 A Right.</p> <p>22 Q I mean, I'm trying to understand what</p> <p>23 you know. Right?</p> <p>24 So -- so are there -- I've tried to pull</p> <p>25 out some things that --</p>	<p>1 A We didn't do -- we didn't do one. I</p> <p>2 mean, there wasn't -- I guess it wasn't thought it</p> <p>3 would help or would be seen favorably coming from</p> <p>4 the industry or --</p> <p>5 Q Okay. Any studies relating to the</p> <p>6 purity of talc from potential carcinogens,</p> <p>7 including asbestos, did you ever sponsor --</p> <p>8 discuss any studies about that?</p> <p>9 A I mean, I think that goes back to when</p> <p>10 the specification was being put in place and all</p> <p>11 the testing was done, and then from then on, it</p> <p>12 was an ongoing work that was done by the industry,</p> <p>13 by the individual companies to --</p> <p>14 Q No, I -- you're thinking of something --</p> <p>15 I'm not talking about testing. I'm talking about</p> <p>16 any publications done to validate and study</p> <p>17 whether or not to test it was effective in</p> <p>18 removing potential carcinogens, including</p> <p>19 asbestos?</p> <p>20 A Any publication?</p> <p>21 Q Yeah.</p> <p>22 A I'm not --</p> <p>23 Q Or studies.</p> <p>24 A -- sure what you mean by publication.</p> <p>25 Q Or studies. Surveys, studies, anything</p>
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<p>1 A Right.</p> <p>2 Q -- I could see from the records.</p> <p>3 A Right.</p> <p>4 Q But I didn't live your life --</p> <p>5 A Right.</p> <p>6 Q -- so I don't know what -- what you</p> <p>7 know.</p> <p>8 A Yeah.</p> <p>9 Q So the question I'm asking you is, do</p> <p>10 you know whether or not, other than the studies</p> <p>11 we've talked about today, are there any other</p> <p>12 studies you can think that -- let's take them one</p> <p>13 at a time -- that were proposed to the PCPC to do</p> <p>14 that would investigate issues relating to ovarian</p> <p>15 cancer and talc?</p> <p>16 A I would say what I'm aware of is the</p> <p>17 group talked about kind of a brainstorming</p> <p>18 session. So not a proposal, not a fleshed-out</p> <p>19 proposal, but is there something we can do.</p> <p>20 Q And what kind of studies were -- were</p> <p>21 raised?</p> <p>22 A I mean, I think was there epidemiology</p> <p>23 work that we could do that -- that would help,</p> <p>24 kind of in a general sense.</p> <p>25 Q Okay. And the answer was?</p>	<p>1 like that.</p> <p>2 A I think that we relied on --</p> <p>3 Q The tests themselves.</p> <p>4 A Right, that the companies were carrying</p> <p>5 out ongoing.</p> <p>6 MR. TISI: All right. If you want to</p> <p>7 take a break, I think I'm done.</p> <p>8 THE VIDEOGRAPHER: The time is 2:44 p.m.</p> <p>9 We're going off the record.</p> <p>10 (Recess.)</p> <p>11 THE VIDEOGRAPHER: The time is 2:51 p.m.</p> <p>12 We're back on the record.</p> <p>13 CROSS-EXAMINATION</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q Good afternoon, Doctor. I'm Richard</p> <p>16 Golomb. We met twice before.</p> <p>17 A Yes.</p> <p>18 Q I'm going to start where Mr. Tisi left</p> <p>19 off, and I'm going to try not to repeat -- repeat</p> <p>20 anything that he did, but I do want to clarify</p> <p>21 some things of where he left off.</p> <p>22 So the Rothman proposal was rejected, as</p> <p>23 you said, because of the cost of that study,</p> <p>24 correct?</p> <p>25 A I'm not sure really it was a proposal.</p>

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<p style="text-align: right;">Page 644</p> <p>1 I think we had gone to them, and they just made it</p> <p>2 clear that it was going to be very, very expensive</p> <p>3 if we wanted -- so we didn't carry it as far as to</p> <p>4 a proposal.</p> <p>5 Q Okay. You said in response to</p> <p>6 Mr. Tisi's question that it was approximately</p> <p>7 \$100,000. Where did you get that number if not</p> <p>8 from a proposal?</p> <p>9 A I -- I just -- just kind of a verbal.</p> <p>10 Q From who?</p> <p>11 A I think J&J actually went back and asked</p> <p>12 him and -- and got a verbal on it.</p> <p>13 Q When -- and when was that?</p> <p>14 A It was after the NTP meeting.</p> <p>15 Q Okay. And were you with -- with PCPC at</p> <p>16 that time?</p> <p>17 A Yes.</p> <p>18 Q All right. So that was shortly after</p> <p>19 you went onboard with PCPC?</p> <p>20 A No, I started -- no, that was in 2000 --</p> <p>21 or probably 2000 -- I'm sure it was 2001.</p> <p>22 Q Okay.</p> <p>23 A I started PCPC in 1997.</p> <p>24 Q All right. And the Wynder/Muscat</p> <p>25 proposal, why was that rejected?</p>	<p style="text-align: right;">Page 646</p> <p>1 learn why it was that one or more of your members</p> <p>2 rejected the Wynder/Muscat study?</p> <p>3 A No.</p> <p>4 Q All right. Now, in -- in addition to</p> <p>5 Rothman and in addition to Wynder and in addition</p> <p>6 to Muscat, there's a Dr. Wehner, correct, or</p> <p>7 Wehner?</p> <p>8 A Wehner, yes.</p> <p>9 Q And that's spelled W-E-H-N-E-R?</p> <p>10 A Correct.</p> <p>11 Q All right. And the Wynder/Muscat</p> <p>12 proposal was sometime in the early to mid-'90s, is</p> <p>13 that your understanding?</p> <p>14 A Whatever it was that I just saw. As I</p> <p>15 say, we never -- we -- PCPC didn't see it, so I</p> <p>16 would rather look at what it was than try to go by</p> <p>17 memory.</p> <p>18 Q Okay. Well, let me ask you this: You</p> <p>19 have -- and I've asked you before about</p> <p>20 Dr. Wehner, and you've reviewed some of the</p> <p>21 documents from him as well, correct?</p> <p>22 A Yes.</p> <p>23 Q And those documents begin in the early</p> <p>24 to mid-1990s, correct?</p> <p>25 A Dr. Wehner did the study at Battelle, so</p>
<p style="text-align: right;">Page 645</p> <p>1 A I -- I don't believe we ever saw that --</p> <p>2 PCPC ever saw that.</p> <p>3 Q But at least one or more of your members</p> <p>4 did?</p> <p>5 A That's what it -- it looked like that</p> <p>6 J&J saw it, yes.</p> <p>7 Q And do you know why -- from your review</p> <p>8 of the records, why that proposal was rejected?</p> <p>9 A No. Again, I don't think we ever saw</p> <p>10 it.</p> <p>11 Q Okay. When you say "we," you say PCPC?</p> <p>12 A Sorry, PCPC. I don't think PCPC ever</p> <p>13 had that.</p> <p>14 Q Okay. My question was a little bit</p> <p>15 different.</p> <p>16 While PCPC may not have seen the</p> <p>17 proposal, one or more of your members did, and</p> <p>18 rejected it, correct?</p> <p>19 A As far as I know the study didn't</p> <p>20 happen, so --</p> <p>21 Q Right.</p> <p>22 A -- that would follow.</p> <p>23 Q And my question was, based on your</p> <p>24 review of the documents that assisted you in your</p> <p>25 preparation for your deposition today, did you</p>	<p style="text-align: right;">Page 647</p> <p>1 that was in the early '80s.</p> <p>2 Q Okay. Well --</p> <p>3 A Or mid-'80s.</p> <p>4 Q -- he was --</p> <p>5 A Mid-'80s.</p> <p>6 Q -- he was retained by the CFTA in the</p> <p>7 early '90s, correct?</p> <p>8 A In addition to doing that study, he was</p> <p>9 retained in 2000, and he was retained at -- he --</p> <p>10 I know we paid for his travel to the IS RTP</p> <p>11 workshop, so that would be the '94.</p> <p>12 Q Okay. And you -- you recall in</p> <p>13 preparation for your deposition last time, you</p> <p>14 told me that you reviewed some of the letters from</p> <p>15 Dr. Wehner, correct?</p> <p>16 A Some of the letters?</p> <p>17 Q Letters.</p> <p>18 A I'm not sure what you mean my letters.</p> <p>19 Q Okay. You don't know what I mean by a</p> <p>20 letter? A letter, it was a piece of paper that</p> <p>21 was -- that came from Dr. Wehner to somebody at</p> <p>22 the CFTA, do you recall that?</p> <p>23 A That was a proposal or --</p> <p>24 Q No, any letter. Do you recall any</p> <p>25 letter from Dr. Wehner to the CFTA?</p>

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<p style="text-align: right;">Page 648</p> <p>1 A I mean, we hired him, so we had</p> <p>2 proposals, I guess. So, yes, documents.</p> <p>3 Q Did -- it's really -- it's not a trick</p> <p>4 question. I'm just trying to understand that</p> <p>5 you -- you in fact saw letters from Dr. Wehner to</p> <p>6 the CFTA outlining what it is that he was</p> <p>7 proposing that be done, correct?</p> <p>8 A I can think of at least one, yes.</p> <p>9 Q Okay. And included in those letters</p> <p>10 were also comments from Dr. Wehner about comments</p> <p>11 that the CFTA -- that Luzenac at that time, the</p> <p>12 predecessor of Imerys, some of the things that</p> <p>13 they were going to say publicly about the defense</p> <p>14 of talc and ovarian cancer, correct? Do you</p> <p>15 recall those?</p> <p>16 A I'm not sure what you mean. I'm --</p> <p>17 Q Okay. Do you recall in one of those</p> <p>18 letters that Dr. Wehner, in addition to</p> <p>19 Dr. Rothman, in addition to Dr. Wynder, in</p> <p>20 addition to Dr. Muscat, that Dr. Wehner also</p> <p>21 recommended that the CFTA and J&J and other</p> <p>22 members of the CFTA at that time also conduct</p> <p>23 their own study?</p> <p>24 A I'm not recalling specifically which</p> <p>25 document you're talking about.</p>	<p style="text-align: right;">Page 650</p> <p>1 case controlled study?</p> <p>2 A Maybe vaguely.</p> <p>3 Q Okay. And do you recall -- does it help</p> <p>4 refresh your recollection that in that letter</p> <p>5 dated in 1994, that in addition to recommending</p> <p>6 the study, Dr. Wehner put some parameters on it</p> <p>7 and said it would be easy to do and that you could</p> <p>8 get the results back within six months?</p> <p>9 A I think that sounds vaguely familiar,</p> <p>10 but I don't remember the details of what -- what</p> <p>11 he was proposing.</p> <p>12 Q And that study was never done, correct?</p> <p>13 A Again, I would really feel better seeing</p> <p>14 what it is, so that -- but a study by doctor -- a</p> <p>15 case controlled study by Dr. Wehner was never</p> <p>16 done, no.</p> <p>17 Q Right. And so -- and a case controlled</p> <p>18 study by Dr. Wynder or Dr. Muscat was never done,</p> <p>19 correct?</p> <p>20 A Again, PCPC was not even aware of that</p> <p>21 proposal.</p> <p>22 Q Okay. Isn't it true that none of these</p> <p>23 studies were done because PCPC and its members</p> <p>24 just didn't want to know the results?</p> <p>25 MR. LOCKE: Objection.</p>
<p style="text-align: right;">Page 649</p> <p>1 Q Okay. Do you -- as you sit here today,</p> <p>2 do you recall that -- whether or not it was in a</p> <p>3 document or not, do you recall that Dr. Wehner</p> <p>4 made a recommendation to the CFTA to do its own</p> <p>5 study?</p> <p>6 A I'm not recalling that right now.</p> <p>7 Q And do you recall that in that letter</p> <p>8 back in 1994 that Dr. Wehner also told the CFTA</p> <p>9 that it would be easy to do and that the results</p> <p>10 would be -- would come back within six months? Do</p> <p>11 you recall that? Does that help refresh your</p> <p>12 recollection?</p> <p>13 A Can you -- can you show me the document,</p> <p>14 because I'm not sure what study you're talking</p> <p>15 about.</p> <p>16 Q Okay. Do --</p> <p>17 A Can you tell me what kind of study</p> <p>18 he's -- he's --</p> <p>19 Q Do you recall Dr. Wehner recommending</p> <p>20 any kind of study?</p> <p>21 A Well, I mean, he did a study for us, and</p> <p>22 he did various assessments of the data, but I</p> <p>23 think you're talking about something real</p> <p>24 specific, and I --</p> <p>25 Q Do you recall Dr. Wehner recommending a</p>	<p style="text-align: right;">Page 651</p> <p>1 THE WITNESS: No. I mean, we take the</p> <p>2 direction of our members, and the members' reasons</p> <p>3 for not funding would -- I mean, you would have to</p> <p>4 ask them.</p> <p>5 BY MR. GOLOMB:</p> <p>6 Q Okay. So sitting here today, you don't</p> <p>7 know why it is that Rothman, Wynder, Muscat and</p> <p>8 Wehner were all rejected, their proposals. Is</p> <p>9 that what you're telling us?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: I think the only thing I</p> <p>12 could say would be the Rothman one, because that's</p> <p>13 one thing we looked at, and we knew that -- again,</p> <p>14 it's not all costs, but we were hoping for just a</p> <p>15 reasonable, normal cost, and that I think -- I'm</p> <p>16 sure we would have gone ahead, but it was in a</p> <p>17 ballpark that was just not rational.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q Okay. And that ballpark was \$100,000?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: That -- that's my</p> <p>22 recollection, yes.</p> <p>23 BY MR. GOLOMB:</p> <p>24 Q All right. And you are aware, are you</p> <p>25 not, that -- that before that decision was made,</p>

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<p style="text-align: right;">Page 652</p> <p>1 that Dr. Cramer had published on the association</p> <p>2 between talc and ovarian cancer, correct?</p> <p>3 A In 1982, yes.</p> <p>4 Q Right. He also published in 1992.</p> <p>5 A I know he published -- he was a coauthor</p> <p>6 on the Gertig paper.</p> <p>7 Q Right. And in that paper, in a footnote</p> <p>8 in that paper he talks about the -- the numbers of</p> <p>9 women who died from ovarian cancer. Do you recall</p> <p>10 that?</p> <p>11 A I do not.</p> <p>12 Q All right. Tell me if this sounds</p> <p>13 familiar: 22,000 women a year had ovarian cancer.</p> <p>14 Does that sound familiar?</p> <p>15 A That sounds like what I heard this</p> <p>16 morning too.</p> <p>17 Q Okay. And 14,000 women a year die from</p> <p>18 ovarian cancer. Does that sound familiar?</p> <p>19 A That sounds about a number I would</p> <p>20 expect from the --</p> <p>21 Q Okay. And in Dr. Cramer's paper in</p> <p>22 1992, he concludes that 10 percent of those women</p> <p>23 die from a -- from talc and ovarian cancer.</p> <p>24 MR. LOCKE: Object --</p> <p>25 BY MR. GOLOMB:</p>	<p style="text-align: right;">Page 654</p> <p>1 Citizen Petition.</p> <p>2 Q Which one?</p> <p>3 A The 2008, so the 2009 response.</p> <p>4 Q So as far as you know, Dr. Huncharek did</p> <p>5 not do any work for PCPC before 2008?</p> <p>6 A I'm just trying to think and make sure</p> <p>7 I'm not skipping anything. I think that's</p> <p>8 correct.</p> <p>9 Q Okay. And how was it that Dr. Huncharek</p> <p>10 was retained by PCPC or one of its members?</p> <p>11 A Again, it was --</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: -- J&J that reached out to</p> <p>14 him first. And they were familiar with him from</p> <p>15 various work.</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q Who was it at J&J?</p> <p>18 A Who did I talk to at J&J at the time? I</p> <p>19 don't remember.</p> <p>20 Q Okay. So in the -- in the deposition</p> <p>21 notice -- and I hate to tell you we're still on</p> <p>22 topic 1, there's only 17 more to go -- but it</p> <p>23 refers to the Weinberg Group. Do you know who the</p> <p>24 Weinberg Group is?</p> <p>25 A Yes.</p>
<p style="text-align: right;">Page 653</p> <p>1 Q Do you recall that in the paper?</p> <p>2 MR. LOCKE: Objection. Mischaracterizes</p> <p>3 the paper.</p> <p>4 BY MR. GOLOMB:</p> <p>5 Q Do you recall that?</p> <p>6 A I -- I recall something along those</p> <p>7 lines. It doesn't mean we agreed with that,</p> <p>8 though.</p> <p>9 Q No, I understand. But that's -- that</p> <p>10 is what was reported in 1992 before the decision</p> <p>11 was made not to do a study that was recommended</p> <p>12 by Dr. Rothman, Dr. Wynder, Dr. Muscat and</p> <p>13 Dr. Wehner?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: I mean, I -- if that's</p> <p>16 what was said in the paper, again, I don't -- I</p> <p>17 would have to look back, and we didn't agree with</p> <p>18 that.</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q All right. So let me ask you about</p> <p>21 Dr. Huncharek, and I'm not going to go through the</p> <p>22 study again. Mr. Tisi did that well.</p> <p>23 When -- when did PCPC first retain</p> <p>24 Dr. Huncharek for any reason?</p> <p>25 A I believe it was for the answer to the</p>	<p style="text-align: right;">Page 655</p> <p>1 Q And who is the Weinberg Group?</p> <p>2 A Weinberg Group is a consulting group,</p> <p>3 and we hired them at the time of the NTP report to</p> <p>4 pull together a binder, organize all the</p> <p>5 information, and then reach out to consulting</p> <p>6 epidemiologists.</p> <p>7 Q All right. And that was in 1999, 2000?</p> <p>8 A It was in 2000.</p> <p>9 Q All right. And was -- did anybody from</p> <p>10 the Weinberg Group talk to Dr. Huncharek at that</p> <p>11 time, do you know?</p> <p>12 A Not that I'm aware of.</p> <p>13 Q Who did they talk to?</p> <p>14 A The people that were hired through the</p> <p>15 Weinberg Group were Drs. Rothman, Pastides, and</p> <p>16 Samet, Dr. Samuel Shapiro, and Dr. Muscat.</p> <p>17 Q All right. And they are -- some or all</p> <p>18 of them were the ones who then wrote the report</p> <p>19 that was then submitted to the NTP?</p> <p>20 A There were three separate reports, and,</p> <p>21 yes, those are the authors. Three of them on one</p> <p>22 and then individuals from Muscat and Shapiro.</p> <p>23 Q All right. And then somebody actually</p> <p>24 made the report to the NTP, correct?</p> <p>25 A Correct.</p>

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<p style="text-align: right;">Page 656</p> <p>1 MR. LOCKE: Objection. This material 2 was covered at length by Mr. Meadows. These 3 questions have been asked and answered. 4 MR. GOLOMB: I don't -- I'm not sure if 5 that's true or not, but I -- I don't -- I only 6 have a couple of minutes on this, so it's not 7 going to take much time. 8 THE WITNESS: Dr. Rothman made a 9 presentation on -- on that that there -- the 10 report that the three of them put together, the 11 review that the three of them put together. 12 BY MR. GOLOMB: 13 Q Okay. And it was -- you're saying -- 14 A So Dr. Pastides, not Dr. Rothman. 15 Q Okay. It was not Dr. Rothman, correct? 16 A That's correct, it was Dr. Pastides. 17 Q In fact, you recall in your review of 18 the documents that Dr. Rothman was kind of upset 19 that he wasn't able to make the presentation? Do 20 you recall that? 21 A Not really. 22 Q Okay. Burson-Marsteller, who is that? 23 A I think they're a -- I think they do 24 work for PCPC on our website or on our -- perhaps 25 on cosmeticsinfo.org. I think --</p>	<p style="text-align: right;">Page 658</p> <p>1 BY MR. GOLOMB: 2 Q Okay. That was an answer? 3 A Yeah, I think they work on our website. 4 I think they work on putting messages together, 5 and they work with our Public Affairs people. 6 Q Well, my question was who is 7 Burson-Marsteller? 8 A It's a company. 9 Q It's a company. All right. And is that 10 something you learned in your preparation for 11 today's deposition? 12 A I had heard of them, the name before. 13 Q All right. Who is Nichols-Dezenhall? 14 A Nichols-Dezenhall is a public affairs 15 company that did work for CTFA back some many 16 years ago. I'm not sure that we've used them at 17 all in recent years. They did a couple of focus 18 groups around the time of the NTP report on talc. 19 We use them I know for other things. 20 Q When did you learn about the focus 21 groups? 22 A In my preparation for this deposition. 23 Q Okay. Because you recall -- I was the 24 one who asked you about Nichols-Dezenhall before, 25 do you remember that?</p>
<p style="text-align: right;">Page 657</p> <p>1 Q I'm sorry? 2 A Perhaps on cosmeticsinfo.org. 3 Q Who -- who are they? 4 A I think they're people that help prepare 5 information, and they work with our Public Affairs 6 department. 7 Q Okay. 8 A I think. 9 Q And so you're -- you're looking like you 10 don't know too much about them. 11 A I don't know too much about them. 12 Q All right. Did you -- you reviewed 13 the -- the notice of deposition before you 14 testified? 15 A Yes. 16 Q And so you know under 1(f), it 17 specifically says that we're going to ask 18 questions about Burson-Marsteller? 19 A Yes. 20 Q Okay. So did you prepare yourself to 21 answer questions about Burson-Marsteller? 22 MR. LOCKE: Why don't you ask her a 23 question about them. 24 MR. GOLOMB: Well, I did. 25 MR. LOCKE: And she answered.</p>	<p style="text-align: right;">Page 659</p> <p>1 MR. LOCKE: When you say "before," what 2 do you mean? 3 THE WITNESS: Yeah. 4 BY MR. GOLOMB: 5 Q In your prior deposition in July of 6 2018. 7 A I -- I couldn't recall who it was, but I 8 do remember being asked about that, and I gave an 9 answer that was not quite accurate, and that's why 10 I made sure I was clarified on that after the 11 fact. 12 Q All right. So did you review your -- 13 your deposition transcript from 2018 to help 14 prepare you today? 15 A I -- I read over it to see if there were 16 any things that I was confused about and made sure 17 I had answers -- my answers correct. 18 Q And I depose you in -- I think it was 19 2016 as well, correct? 20 A That's correct. 21 Q Did you review that in preparation for 22 your deposition today? 23 A Not today, no. 24 Q I also after your deposition in July of 25 2018 and before today depose Mr. Pollack. You</p>

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<p style="text-align: right;">Page 660</p> <p>1 know him, correct?</p> <p>2 A Yes.</p> <p>3 Q And just for the ladies and gentlemen of</p> <p>4 the jury, can you explain who Mr. Pollack is.</p> <p>5 A Mark Pollack is -- I should know his</p> <p>6 title, but he is an employee of the Personal Care</p> <p>7 Products Council. He reports directly to our CEO.</p> <p>8 He has an executive VP title. Perhaps it's for</p> <p>9 membership. I'm not sure.</p> <p>10 Q Okay. And did you read Mr. Pollack's</p> <p>11 deposition transcript?</p> <p>12 A I did not.</p> <p>13 Q All right. Can we go to document 50 --</p> <p>14 52415.</p> <p>15 This was a composite document. Which</p> <p>16 has been marked as Exhibit 70.</p> <p>17 (Exhibit No. 70 was marked for</p> <p>18 identification.)</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q To me it appears to be a -- it's a PCPC</p> <p>21 document, and to me it appears to be a PowerPoint</p> <p>22 of some sort.</p> <p>23 Have you seen this before?</p> <p>24 A I may have seen it in my preparation.</p> <p>25 I'm not sure.</p>	<p style="text-align: right;">Page 662</p> <p>1 52418.</p> <p>2 Which is part of the same composite,</p> <p>3 correct?</p> <p>4 A Yes, so it appears.</p> <p>5 Q And it says: "Mission accomplished by</p> <p>6 promoting," and then the first bullet point says:</p> <p>7 "Voluntary industry self-regulation."</p> <p>8 Is that still a primary mission of PCPC?</p> <p>9 A I guess I would probably say no in the</p> <p>10 fact that we have been working on getting updated</p> <p>11 regulations passed for the cosmetic industry for</p> <p>12 the past 12 years.</p> <p>13 Q Well, let's go to the next document,</p> <p>14 which is PCPC 52424.</p> <p>15 And it says at the top "Self-regulation</p> <p>16 Programs," and under the first bullet point it</p> <p>17 says "CIR," correct?</p> <p>18 A Yes.</p> <p>19 Q All right. And CIR is still a</p> <p>20 self-regulatory program that is funded by the</p> <p>21 PCPC, correct?</p> <p>22 A It is still funded by the PCPC, correct.</p> <p>23 Q And it's still a self-regulatory</p> <p>24 program, correct?</p> <p>25 A I guess you could call it that. I mean,</p>
<p style="text-align: right;">Page 661</p> <p>1 Q Okay. Can you tell us what it is?</p> <p>2 A Well, it looks like it's kind of an</p> <p>3 introduction to what is -- what is CTFA.</p> <p>4 Obviously, this is older since we're now PCPC.</p> <p>5 MR. LOCKE: And just for the record, I</p> <p>6 want to note it's missing quite a few pages, and</p> <p>7 some pages -- well --</p> <p>8 MR. TISI: Right. And for the record,</p> <p>9 it was about a 50-page document, and the ones I</p> <p>10 made copies of are the ones I'm asking questions</p> <p>11 about.</p> <p>12 BY MR. GOLOMB:</p> <p>13 Q Is there anything, based on your review</p> <p>14 of those documents, that can tell us when this was</p> <p>15 used?</p> <p>16 A No. That's to say, only from CTFA that</p> <p>17 tells you something.</p> <p>18 Q Right. So when did CTFA change to PCPC?</p> <p>19 A Roughly 2006.</p> <p>20 Q Now, did you ever see this document</p> <p>21 before you were preparing for this deposition?</p> <p>22 A I doubt it.</p> <p>23 Q So do you know who prepared it?</p> <p>24 A No.</p> <p>25 Q Let's go to the next document, which is</p>	<p style="text-align: right;">Page 663</p> <p>1 we -- we undertook CIR because FDA didn't. So...</p> <p>2 Q The next document in that same</p> <p>3 PowerPoint is PCPC 52426.</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q And it basically is talking about the --</p> <p>7 the trade association obviously being at that time</p> <p>8 CTFA, now PCPC, and some of the -- the member</p> <p>9 services, correct?</p> <p>10 A Yes.</p> <p>11 Q And the first bullet point provides</p> <p>12 current information?</p> <p>13 A Yes.</p> <p>14 Q The second extends your resources,</p> <p>15 meaning that you can pull your resources like as</p> <p>16 in a task force.</p> <p>17 A That's one way, yes.</p> <p>18 MR. LOCKE: Objection.</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q And then the third bullet point is --</p> <p>21 allows you to influence industry policy and</p> <p>22 action. Correct?</p> <p>23 A Yes.</p> <p>24 Q And allows you to avoid direct</p> <p>25 company-government confrontation.</p>

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<p style="text-align: right;">Page 664</p> <p>1 A That's what it says.</p> <p>2 Q Right. So meaning that PCPC, or at that</p> <p>3 time CFTA, kind of acted as the intermediary to</p> <p>4 deal with the government confrontation?</p> <p>5 A For example, comments where the</p> <p>6 companies would -- where we would coordinate</p> <p>7 and -- and we would submit comments.</p> <p>8 Q Correct. Or as in this case, where</p> <p>9 the -- the CFTA would put its name on a document</p> <p>10 so that J -- J&J didn't have to.</p> <p>11 MR. LOCKE: Objection.</p> <p>12 THE WITNESS: We were -- we were the</p> <p>13 face of -- we were serving as the face of the</p> <p>14 industry.</p> <p>15 BY MR. GOLOMB:</p> <p>16 Q Right. And in this case, though, you</p> <p>17 were serving as the face of the industry at the</p> <p>18 specific request of J&J, who said -- who basically</p> <p>19 concurred with the report that they reviewed, but</p> <p>20 suggested that it shouldn't be their name on it,</p> <p>21 it should be your name on it, correct?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: We had to agree with the</p> <p>24 report as well.</p> <p>25 BY MR. GOLOMB:</p>	<p style="text-align: right;">Page 666</p> <p>1 clearance required.</p> <p>2 A There's no premarket approval, that's</p> <p>3 correct.</p> <p>4 Q As opposed to a pharmaceutical which</p> <p>5 does.</p> <p>6 A That the active ingredients would be</p> <p>7 approved, yes.</p> <p>8 Q Right. Cosmetics have less rigorous</p> <p>9 inspections --</p> <p>10 A Yes.</p> <p>11 Q -- than a pharmaceutical.</p> <p>12 And cosmetics have no specific standards</p> <p>13 for efficacy.</p> <p>14 A Well, cosmetics don't have efficacy the</p> <p>15 same way that drugs do, so that just kind of</p> <p>16 follows.</p> <p>17 Q Correct. That's part of the</p> <p>18 self-regulatory standard.</p> <p>19 A No, I mean, cosmetics are not -- they</p> <p>20 don't affect the structure or function of the</p> <p>21 body. That's by definition. So they don't have</p> <p>22 efficacy in a way that a drug would.</p> <p>23 Q Let's turn to 52505.</p> <p>24 Well, that's it, but it's upside down on</p> <p>25 the screen. There you go.</p>
<p style="text-align: right;">Page 665</p> <p>1 Q All right. But that's to allow them to</p> <p>2 avoid direct company-government confrontation,</p> <p>3 correct?</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: I'm not sure that would be</p> <p>6 confrontation, but -- but, yes, we were the face</p> <p>7 of the industry.</p> <p>8 BY MR. GOLOMB:</p> <p>9 Q All right. And the next document is</p> <p>10 52457.</p> <p>11 This is essentially kind of describes</p> <p>12 the differences, does it not, between cosmetic and</p> <p>13 the pharmaceutical?</p> <p>14 A In some ways, yes. And I have to say</p> <p>15 this -- this is out of date. I mean, we would not</p> <p>16 produce something like this today.</p> <p>17 Q But it's still holds true, though. You</p> <p>18 may not produce it, but it still holds true.</p> <p>19 A Well, but -- no, what I'm saying is, for</p> <p>20 example, in this legislation that we are</p> <p>21 advocating for -- good manufacturing practices are</p> <p>22 a part of that, just as an example. So things</p> <p>23 change.</p> <p>24 Q But one -- one of the things that still</p> <p>25 holds true is that cosmetics have no prior FDA</p>	<p style="text-align: right;">Page 667</p> <p>1 So when this describes expert panels, it</p> <p>2 talks about liaison members, and I assume, correct</p> <p>3 me if I'm wrong, this is liaisoned from the -- at</p> <p>4 the time the CFTA to various governmental</p> <p>5 agencies, correct?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: I'm sorry. These are --</p> <p>8 yeah, there's three liaison members that still</p> <p>9 exist today. One is from FDA, one is from</p> <p>10 Consumer Federation of America, and one is</p> <p>11 representing industry.</p> <p>12 BY MR. GOLOMB:</p> <p>13 Q Right. And these -- and so there was a</p> <p>14 lot of talk about John Bailey today.</p> <p>15 A Yes.</p> <p>16 Q So this is at a time when John Bailey</p> <p>17 was still at the FDA, correct?</p> <p>18 A Correct.</p> <p>19 Q And I want to understand the timeline of</p> <p>20 this. So with -- specifically with John Bailey.</p> <p>21 The -- the first Citizens Petition was</p> <p>22 in 1993, correct?</p> <p>23 A Yes.</p> <p>24 Q And that was at a time that John Bailey</p> <p>25 was at the FDA, correct?</p>

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<p>1 A Yes.</p> <p>2 Q And as -- as we saw from the letter,</p> <p>3 John Bailey at some point, representing the FDA,</p> <p>4 wrote a letter not rejecting the Citizens Petition</p> <p>5 but, rather, saying they didn't have the resources</p> <p>6 to deal with it at that time, correct?</p> <p>7 A I think that was just the initial</p> <p>8 response.</p> <p>9 Q The initial response in 1993, that's</p> <p>10 what I'm talking about.</p> <p>11 A Right, which is -- but that's -- I mean,</p> <p>12 that's how they respond to Citizens Petitions</p> <p>13 initially, I think almost always.</p> <p>14 Q I'm not -- I'm not questioning it one</p> <p>15 way or the other. I'm just trying to understand</p> <p>16 the timeline.</p> <p>17 A He wrote that initial letter in</p> <p>18 response, yes.</p> <p>19 Q Right. When he was -- when he was at</p> <p>20 the FDA.</p> <p>21 A At FDA, Yes.</p> <p>22 Q And then he gets hired by the CFTA when?</p> <p>23 A Okay. Let's see. I started in '97.</p> <p>24 It's like 2000 and -- let's see. He took my</p> <p>25 boss -- old boss's job in 2000 and --</p>	<p>1 A Correct.</p> <p>2 Q -- to the CFTA or the PCPC.</p> <p>3 A Correct.</p> <p>4 Q And that was after -- after he came to</p> <p>5 the PCPC, and Bailey set up the meeting with the</p> <p>6 FDA, correct?</p> <p>7 MR. LOCKE: Objection. Asked and</p> <p>8 answered.</p> <p>9 THE WITNESS: Right. When he came to</p> <p>10 the -- he eventually set up the meeting in 2009.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q Right. And after he set up the meeting</p> <p>13 with his old subordinates, that's when the -- the</p> <p>14 Citizens Petition was rejected, correct?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: I think there were other</p> <p>17 things that went on in the meantime. For example,</p> <p>18 the assessment of the talcs -- admittedly not</p> <p>19 exhaustive, but the assessment of talcs for</p> <p>20 asbestos.</p> <p>21 BY MR. GOLOMB:</p> <p>22 Q Well, but at that point in 2008, there</p> <p>23 had been 24 or more studies that already looked at</p> <p>24 the association between talc and ovarian cancer,</p> <p>25 and something like 18 of those studies showed a</p>
Page 669	Page 671
<p>1 Q If you can speak up so that the --</p> <p>2 A I'm just ruminating instead of silence.</p> <p>3 Q Yeah, I know, but if you're going to</p> <p>4 ruminate out loud, you have to say it so the court</p> <p>5 reporter can get it.</p> <p>6 A Just trying to figure out -- it would</p> <p>7 have been roughly 2003, '2.</p> <p>8 Q Okay. And between 1993 and 2002 or</p> <p>9 2003, when Bailey came from the FDA to the CFTA,</p> <p>10 there had been no response to the Citizens</p> <p>11 Petition other than, We don't have the resources,</p> <p>12 correct?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I thought there was a</p> <p>15 response.</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q And what was the response?</p> <p>18 A I thought the initial one was rejected.</p> <p>19 Q Okay. And is that something you saw</p> <p>20 today?</p> <p>21 A No, I haven't seen it today. We just</p> <p>22 saw the latter one today, the 2008, that was</p> <p>23 responded to in 2014.</p> <p>24 Q Right. And that was after Bailey had</p> <p>25 already come from the FDA --</p>	<p>1 statistically significant association between talc</p> <p>2 and ovarian cancer, correct?</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: I would say there were --</p> <p>5 it's -- it's much more -- it's more complex than</p> <p>6 that. I mean, there were other issues, as have</p> <p>7 been pointed out, of biologic plausibility, of</p> <p>8 dose-response. So it's a little -- not as</p> <p>9 straightforward as that.</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q Well, understood. I mean, we -- we -- I</p> <p>12 think we can agree that during this period of time</p> <p>13 between, you know, 1982 and 2008, that while there</p> <p>14 were all these other studies that were coming out,</p> <p>15 more than two dozen studies, most of which showed</p> <p>16 the statistically significant association, while</p> <p>17 at the same time Johnson & Johnson and the PCPC</p> <p>18 were rejecting case controlled studies of their</p> <p>19 own, but at that -- during that period of time,</p> <p>20 industry chose, rather than doing its own study,</p> <p>21 to do a critical analysis of the individual</p> <p>22 studies, correct?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: We did do critical</p> <p>25 analyses of the individual studies, yes.</p>

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<p style="text-align: right;">Page 672</p> <p>1 BY MR. GOLOMB:</p> <p>2 Q And -- but did not do its own study.</p> <p>3 A We did not do an epidemiology study.</p> <p>4 Q Mr. Tisi asked you before about the</p> <p>5 standard, and I've asked you about this before, so</p> <p>6 I'm not going to go into a lot of detail about it.</p> <p>7 But it's a document which was previously</p> <p>8 marked for identification as Plaintiff's Exhibit</p> <p>9 324 --</p> <p>10 MR. GOLOMB: Okay. That's fine.</p> <p>11 -- which we will mark as Exhibit 71.</p> <p>12 (Exhibit No. 71 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q All right. This is the Code of Federal</p> <p>16 Regulations, Title 21. Are you familiar with</p> <p>17 this?</p> <p>18 A Yes.</p> <p>19 Q Were you aware of this before I asked</p> <p>20 you about it?</p> <p>21 A I -- I'm not familiar with specifically</p> <p>22 these labeling requirements, and we don't get into</p> <p>23 issues of labeling beyond telling our -- helping</p> <p>24 our companies understand what current labeling</p> <p>25 requirements are in our labeling manual.</p>	<p style="text-align: right;">Page 674</p> <p>1 THE WITNESS: Yeah, we don't -- PCPC</p> <p>2 does not get into labeling.</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Right. And as far as you know, the FDA</p> <p>5 also doesn't tell a company what to put on a</p> <p>6 label, correct?</p> <p>7 MR. LOCKE: Objection. Beyond the</p> <p>8 scope.</p> <p>9 THE WITNESS: I mean, the FDA opined on</p> <p>10 the Citizens Petitions.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q Well, but they don't tell the company</p> <p>13 when -- when to put a label on and when not to,</p> <p>14 correct?</p> <p>15 MR. LOCKE: Objection. Beyond the</p> <p>16 scope.</p> <p>17 THE WITNESS: I really don't know.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q All right. Did you at any time in</p> <p>20 preparation for any of these depositions read the</p> <p>21 testimony of Dr. Bailey?</p> <p>22 A I did not.</p> <p>23 Q Okay. Were you aware that Dr. Bailey</p> <p>24 has testified not in a -- in an ovarian cancer</p> <p>25 case, but in an asbestos case where he discussed</p>
<p style="text-align: right;">Page 673</p> <p>1 Q Okay. But I -- I've asked you about</p> <p>2 this before, correct? Do you recall that?</p> <p>3 A I -- I -- I don't recall specifically.</p> <p>4 Q All right. This is the Code of Federal</p> <p>5 Regulations, Title 21, Section 740.1,</p> <p>6 "Establishment of Warning Statements."</p> <p>7 Did I read that correctly?</p> <p>8 A Yes.</p> <p>9 Q And can you just read subsection (a) for</p> <p>10 the jury, please.</p> <p>11 A "The label of a cosmetic product shall</p> <p>12 bear a warning statement whenever necessary or</p> <p>13 appropriate to prevent a health hazard that may be</p> <p>14 associated with the product."</p> <p>15 Q "That may be associated with the</p> <p>16 product," correct?</p> <p>17 A That's what it says.</p> <p>18 Q All right. And that is a determination</p> <p>19 of whether or not a company is going to label a</p> <p>20 cosmetic product with a warning statement. That</p> <p>21 is a decision to be made by the company, correct?</p> <p>22 A That's --</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: That's not something --</p> <p>25 MR. LOCKE: Beyond the scope.</p>	<p style="text-align: right;">Page 675</p> <p>1 very specifically the role of the FDA in</p> <p>2 cosmetics?</p> <p>3 MR. LOCKE: Objection.</p> <p>4 You can answer.</p> <p>5 THE WITNESS: I mean, I knew he</p> <p>6 testified. I don't know any specifics beyond</p> <p>7 that.</p> <p>8 BY MR. GOLOMB:</p> <p>9 Q All right. I want to move to topic 7,</p> <p>10 which is the National Cancer Institute.</p> <p>11 What is the National Cancer Institute?</p> <p>12 A It's a governmental agency. I'm not</p> <p>13 sure "agency" is the right word. It's a</p> <p>14 governmental body that I believe funds cancer</p> <p>15 research.</p> <p>16 Q And what -- what, if any,</p> <p>17 communications, directly or indirectly, does the</p> <p>18 PCPC have with the NCI generally?</p> <p>19 A I'm not aware of any.</p> <p>20 Q At any time?</p> <p>21 A I'm not aware of any, no, at any time.</p> <p>22 Q All right. Have you ever -- and I'm</p> <p>23 not -- when I say "you," I'm talking about anybody</p> <p>24 at PCPC because that's your role here today --</p> <p>25 A Yes.</p>

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<p style="text-align: right;">Page 676</p> <p>1 Q -- to testify on behalf of PCPC. 2 Have you had any contact with a member 3 organization, be it J&J, Luzenac, Rio Tinto, 4 Imerys, or any other member, where you have 5 learned that they've had contact with the NCI? 6 A Not that I'm aware of. 7 Q So when the NCI on a number of occasions 8 on their website identifies talc as a risk of 9 ovarian cancer, and then that was taken off the 10 website, you have no idea why? 11 A Correct. 12 MR. LOCKE: Objection. 13 BY MR. GOLOMB: 14 Q Okay. Were you -- were you aware of 15 that before I just told you that? 16 A I was, and I can't remember how I became 17 aware of that. I'm not sure I was ever aware that 18 it was on. I was maybe aware that it was off. 19 But I -- I don't recall -- 20 Q Have you ever -- 21 A -- when I learned that. 22 Q I'm sorry. I didn't mean to interrupt. 23 A Oh, no, since I don't -- I'm not aware 24 of when I learned that. I mean, I just can't 25 remember.</p>	<p style="text-align: right;">Page 678</p> <p>1 A I wouldn't have because I am absolutely 2 certain they would not do that without talking to 3 the Science department. 4 Q And why do you say that? 5 A Because that's just the way we work. I 6 mean, when -- when the Public Affairs, for 7 example, is doing any kind of a science issue, 8 they're consulting with us. They're not doing 9 that on their own. 10 Q Let's go to the next document, which 11 we'll mark as Exhibit 72. 12 (Exhibit No. 72 was marked for 13 identification.) 14 BY MR. GOLOMB: 15 Q And this again is -- 16 (Counsel conferring.) 17 BY MR. GOLOMB: 18 Q Yeah, it's been previously marked for 19 identification as P-72. It's up on the screen. 20 (Counsel conferring.) 21 BY MR. GOLOMB: 22 Q Now, this was the NCI website as of 23 September 15th, 2011. You can see that from the 24 lower right-hand corner. Do you see that? 25 A Yes.</p>
<p style="text-align: right;">Page 677</p> <p>1 Q Okay. Have you ever looked at the NCI 2 website for any reason? 3 A I think I looked at that having heard 4 about that. 5 Q Well, you have a -- my word, not 6 yours -- I know we have previously gone through 7 the organizational chart in great detail, and 8 there was a Public Relations/Communications 9 department, correct? 10 A On -- on our website? 11 Q On PCPC. 12 A We have -- yes. 13 Q Right. And in preparation for this 14 deposition, you were asked very specifically about 15 communications, directly or indirectly, with the 16 NCI concerning the risk of ovarian cancer caused 17 by application of talcum powder. 18 A Okay. Yes. 19 Q And so in your role as a 30(b)(6) 20 witness, did you go to any of the employees within 21 the Communications department, Public Relations 22 department, whatever you call it, as well as 23 the -- the -- and again my word, not yours -- the 24 lobbying arm of PCPC to find out if they had any 25 communications with the NCI?</p>	<p style="text-align: right;">Page 679</p> <p>1 Q And this is the "Ovarian Cancer 2 Prevention, PDQ, Prevention Patient Information." 3 Do you see that? 4 A Yes. 5 Q Now, are you familiar with the PDQ? 6 A Um -- 7 Q Not this one in particular. A PDQ 8 generally. 9 A I'm trying to -- I'm not sure I know 10 what it stands for. I think, again, because I've 11 seen something along these lines, I -- 12 Q It's a Physician's Data Query. 13 A Okay. 14 Q Does that sound familiar? 15 A Yeah, it does now. Yeah. 16 Q Okay. And so in order to go on to the 17 website and go specifically to the PDQ, you have 18 to be a physician or scientist that has access. 19 Is that consistent with your understanding? 20 MR. LOCKE: Objection. Beyond the 21 scope. 22 THE WITNESS: Yeah, I just wouldn't have 23 known that. 24 BY MR. GOLOMB: 25 Q Okay. And that's fine, by the way. If</p>

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<p>1 you don't know, it's --</p> <p>2 A Right. I don't know.</p> <p>3 Q So that if a -- a woman who has ovarian</p> <p>4 cancer and is claiming that she got her ovarian</p> <p>5 cancer from the use of talcum powder, she would</p> <p>6 not, unless she was a physician or a scientist,</p> <p>7 have access to the PDQ. Is that consistent with</p> <p>8 your understanding?</p> <p>9 MR. LOCKE: Objection. Beyond the</p> <p>10 scope.</p> <p>11 THE WITNESS: I think only just from</p> <p>12 what you just said, that access is limited to</p> <p>13 physicians, so...</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q Okay. Well, on the other hand, if</p> <p>16 anybody went on to the NCI website, and in the</p> <p>17 search box typed in "ovarian cancer," they would</p> <p>18 get a -- a Snapshot of Ovarian Cancer. Is that</p> <p>19 consistent with your understanding?</p> <p>20 MR. LOCKE: Objection. Beyond the</p> <p>21 scope.</p> <p>22 THE WITNESS: I guess. Again, I'm not</p> <p>23 sure.</p> <p>24 BY MR. GOLOMB:</p> <p>25 Q Okay. So if you take a look at</p>	<p>1 the NCI as of September 5th, 2011, correct?</p> <p>2 MR. LOCKE: Objection. Beyond the</p> <p>3 scope.</p> <p>4 THE WITNESS: September 15th, but yes.</p> <p>5 BY MR. GOLOMB:</p> <p>6 Q 2011.</p> <p>7 A That's -- that's the date of this</p> <p>8 document, yes.</p> <p>9 Q Okay. Now, let's go to the next</p> <p>10 document, which is MBS-CRE271.</p> <p>11 (Exhibit No. 73 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. GOLOMB:</p> <p>14 Q Have you seen that before?</p> <p>15 A I saw it in preparation for this.</p> <p>16 Q Okay. Do you need time to review it now</p> <p>17 or --</p> <p>18 A Yes.</p> <p>19 Q -- or are you familiar with it?</p> <p>20 A No, I need time to review it.</p> <p>21 Q Go ahead.</p> <p>22 A (Peruses document.) Okay.</p> <p>23 Q This is an e-mail exchange back in April</p> <p>24 of 2013 between William Kelly, Jr., and Jim Tozzi,</p> <p>25 correct?</p>
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<p>1 Exhibit -- what was it 72? -- if you take a look</p> <p>2 at Exhibit 72 --</p> <p>3 A Okay.</p> <p>4 Q -- this is the PDQ on ovarian cancer</p> <p>5 prevention, correct?</p> <p>6 MR. LOCKE: Just to be clear, it's</p> <p>7 pages 1 and 3 of a seven-page document.</p> <p>8 MR. GOLOMB: Correct. And that was to</p> <p>9 show the cover page and the portions relevant to</p> <p>10 talc.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q So if you go to page 3 of that document,</p> <p>13 in the middle of the document it refers to talc.</p> <p>14 Do you see that?</p> <p>15 A I do see that.</p> <p>16 Q And it says: "The use of talc may</p> <p>17 increase the risk of ovarian cancer. Talcum</p> <p>18 powder dusted on the perineum, the area between</p> <p>19 the vagina and the anus, may reach the ovaries by</p> <p>20 entering the vagina."</p> <p>21 Do you see that?</p> <p>22 A That's what it says, yes.</p> <p>23 Q Did I read that correctly?</p> <p>24 A Yes.</p> <p>25 Q So that was a -- posted on the PDQ of</p>	<p>1 A Correct.</p> <p>2 Q Who is William Kelly, Jr.?</p> <p>3 A He is with the CRE.</p> <p>4 Q And who is Jim Tozzi?</p> <p>5 A Also with CRE, I believe.</p> <p>6 Q And if you look at the middle e-mail on</p> <p>7 page 1 of 2, from Jim Tozzi to Bill Kelly,</p> <p>8 April 15th, 2013, at 11:12 a.m. Do you see that?</p> <p>9 A Yes.</p> <p>10 Q It says -- the second -- the last line</p> <p>11 on that e-mail says: "Showing that the CIR as</p> <p>12 unbiased and cleaning up material on the internet</p> <p>13 is critical if they are going to calm down</p> <p>14 lawsuits."</p> <p>15 A That's what it says.</p> <p>16 Q Do you know what he's referring to when</p> <p>17 he says "cleaning up material on the internet"?</p> <p>18 MR. LOCKE: Objection. Beyond the</p> <p>19 scope.</p> <p>20 THE WITNESS: I don't. We didn't see</p> <p>21 this. We never talked to them about this.</p> <p>22 BY MR. GOLOMB:</p> <p>23 Q And do you know what he means by "calm</p> <p>24 down lawsuits"?</p> <p>25 MR. LOCKE: Same objection.</p>

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<p>1 THE WITNESS: I mean, obviously he is</p> <p>2 referring to litigation, I presume. But --</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Okay. Well, are you aware one way or</p> <p>5 the other as to whether or not there was any</p> <p>6 litigation in which any of these companies were</p> <p>7 sued as a result of the -- the relationship</p> <p>8 between talc and ovarian cancer as of April 13 --</p> <p>9 April 15th, 2013?</p> <p>10 MR. LOCKE: When you say "any of these</p> <p>11 companies," to whom are you referring?</p> <p>12 MR. GOLOMB: J&J and Imerys and their</p> <p>13 predecessors.</p> <p>14 MR. LOCKE: Objection. Beyond the</p> <p>15 scope.</p> <p>16 THE WITNESS: Yeah, I don't know the</p> <p>17 dates of lawsuits, and I -- I just don't know.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q Okay. The -- on the bottom of the page,</p> <p>20 there's an e-mail from William Kelly, Jr., to</p> <p>21 Tozzi on April 15th, 2013, just 24 minutes before,</p> <p>22 at 12:48 p.m.</p> <p>23 Do you see that?</p> <p>24 A Yes.</p> <p>25 Q And if we look at the second paragraph</p>	<p>1 assume because it's an unusual name, that's who he</p> <p>2 is talking about, yes.</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q All right. And do you know -- do you</p> <p>5 know Mr. Sharma?</p> <p>6 A I may have been on a phone call with him</p> <p>7 once or twice, but I don't know if I've met him.</p> <p>8 Q All right. Have you ever spoken to him</p> <p>9 specifically about talc and its association with</p> <p>10 ovarian cancer?</p> <p>11 A As I said, I may have been on a phone</p> <p>12 call, and I can't remember context, but -- I mean,</p> <p>13 it'd be on a conference call. I don't believe</p> <p>14 I've ever spoken to him one on one.</p> <p>15 Q All right. And if we look at the last</p> <p>16 sentence going on to the next, the first sentence</p> <p>17 of the next page, it says: "Shripal knows that we</p> <p>18 engineered the CIR report from the outset."</p> <p>19 Did I read that correctly?</p> <p>20 A That's what it says.</p> <p>21 Q And that's from one CRE employee to</p> <p>22 another?</p> <p>23 A That's what it looks like.</p> <p>24 Q Let -- let's take a look at the next</p> <p>25 document, which was previously marked for</p>
Page 685	Page 687
<p>1 that begins: "The only account I am working on</p> <p>2 currently is talc." Do you see that?</p> <p>3 A Yes.</p> <p>4 Q And that is -- that's William Kelly, Jr.</p> <p>5 saying that, correct?</p> <p>6 A Yes.</p> <p>7 Q And in the -- it says: "The only</p> <p>8 account I am working on currently is talc. Of</p> <p>9 course, I also want to write an article on the IQA</p> <p>10 during the next six months as well as clean up the</p> <p>11 Wikipedia entry on the IQA."</p> <p>12 What is the IQA?</p> <p>13 A I have --</p> <p>14 MR. LOCKE: Objection. Beyond the</p> <p>15 scope.</p> <p>16 THE WITNESS: I don't know.</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q And then it refers to somebody named</p> <p>19 Shripal. Do you see that?</p> <p>20 A Yeah -- yes.</p> <p>21 Q Who is that?</p> <p>22 A Shripal is somebody at Imerys.</p> <p>23 Q Right, that's Shripal Sharma, correct?</p> <p>24 MR. LOCKE: Objection.</p> <p>25 THE WITNESS: I -- I mean, I would</p>	<p>1 identification as Plaintiff's Exhibit P-225.</p> <p>2 (Exhibit No. 74 was marked for</p> <p>3 identification.)</p> <p>4 BY MR. GOLOMB:</p> <p>5 Q This is another Ovarian Cancer</p> <p>6 Prevention PDQ, correct?</p> <p>7 A Yes.</p> <p>8 Q And you'll see on the bottom right-hand</p> <p>9 corner it's dated June 12, 2013.</p> <p>10 A Yes.</p> <p>11 Q Approximately two years after the last</p> <p>12 one I showed you.</p> <p>13 A Approximately.</p> <p>14 Q And if you go on to the next page,</p> <p>15 towards the bottom quarter of the page, it refers</p> <p>16 to talc, correct?</p> <p>17 A I only have page 1.</p> <p>18 Q I'm going to hand you my copy and ask</p> <p>19 you to turn to page 2.</p> <p>20 Do you see the highlighted area?</p> <p>21 A Yes.</p> <p>22 Q Can you just read that for the jury,</p> <p>23 please.</p> <p>24 A It says, quote: "The use of talc may</p> <p>25 increase the risk of ovarian cancer. Talcum</p>

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<p style="text-align: right;">Page 688</p> <p>1 powder dusted on the perineum, the area between 2 the vagina and the anus, may reach the ovaries by 3 entering the vagina." 4 Q Okay. And that was in June of 2013, 5 after the first of the lawsuits in the -- in these 6 cases were filed. Are you aware of that? 7 MR. LOCKE: Objection. Beyond the 8 scope. 9 THE WITNESS: I'm not aware of the 10 dates, no. 11 BY MR. GOLOMB: 12 Q Okay. Let me show you the next 13 document, which has been marked as P-384. 14 (Exhibit No. 75 was marked for 15 identification.) 16 BY MR. GOLOMB: 17 Q This is another Ovarian Cancer 18 Prevention PDQ, correct? 19 A Yes. 20 Q All right. And this is a little bit 21 different format taken from the website than 22 previous ones, correct? 23 A Yes. 24 Q And do you see the -- the date of this 25 in the bottom of the page?</p>	<p style="text-align: right;">Page 690</p> <p>1 the vagina and the anus, may reach the ovaries by 2 entering the vagina." 3 Q Okay. Thank you. 4 Let me show you the next document. 5 And this is a document which has been 6 previously marked for identification as P-385. 7 (Exhibit No. 76 was marked for 8 identification.) 9 BY MR. GOLOMB: 10 Q Have you seen this document before? 11 A Not that I know of, no. 12 Q All right. Now, you'll see at the 13 bottom this document was dated March 19th, 2015. 14 Do you see that? 15 A Yes. 16 Q And this is after the IARC report that 17 came out and declared talc a Class 2B carcinogen, 18 correct? 19 MS. FRAZIER: Object to form. 20 MR. LOCKE: Objection. I'm not going to 21 direct the witness not to answer, but she's 22 testified she has not seen these exhibits 23 previously. I'm -- there's a lack of foundation. 24 It's beyond the scope. 25 You can answer to the extent you can.</p>
<p style="text-align: right;">Page 689</p> <p>1 A It's hard to read, but it's, I think, 2 August 18, 2014. 3 Q And at the top of the page, it says: 4 "The following risk factors may increase the risk 5 of ovarian cancer." Do you see that? 6 A I do. 7 Q And the -- the fifth risk factor there 8 is what? 9 A It says -- 10 MR. LOCKE: Objection. Beyond the 11 scope. 12 BY MR. GOLOMB: 13 Q Is what? 14 A It says "talc." 15 Q And from the same document, page 2 of 3, 16 it specifically refers to talc, correct? 17 MR. LOCKE: Objection. Beyond the 18 scope. 19 THE WITNESS: Yes. 20 BY MR. GOLOMB: 21 Q And can you just read that for the jury, 22 please. 23 A It says, quote: "The use of talc may 24 increase the risk of ovarian cancer. Talcum 25 powder dusted on the perineum, the area between</p>	<p style="text-align: right;">Page 691</p> <p>1 THE WITNESS: And so what was the 2 question? 3 BY MR. GOLOMB: 4 Q This document is dated March 19th, 5 2015 -- 6 A Correct. 7 Q -- which is after the IARC report came 8 out, correct? 9 A Yes. 10 Q The IARC report which announced that 11 the -- they concluded that talc was a Class 2B 12 carcinogen, correct? 13 MR. LOCKE: Objection. 14 THE WITNESS: Based on limited evidence. 15 BY MR. GOLOMB: 16 Q And in fact, this Ovarian Cancer 17 Prevention PDQ that we're now referring to refers 18 to the IARC report, correct? 19 MR. LOCKE: Objection. 20 THE WITNESS: Yes. 21 BY MR. GOLOMB: 22 Q And do you see at the bottom third of 23 the page, it says "Perineal Talc Exposure"? 24 A Yes. 25 MR. LOCKE: Objection.</p>

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<p style="text-align: right;">Page 692</p> <p>1 BY MR. GOLOMB:</p> <p>2 Q Can you just read that for us, please.</p> <p>3 A It says, quote: "Based on solid</p> <p>4 evidence, perineal application of talc is</p> <p>5 associated with a small increased risk of ovarian</p> <p>6 cancer. The International Agency for Research on</p> <p>7 Cancer has concluded that perineal talc is a</p> <p>8 possible carcinogen."</p> <p>9 Q And then it talks about the magnitude of</p> <p>10 the effects, correct?</p> <p>11 A It does.</p> <p>12 Q And it says an odds ratio of 1.24,</p> <p>13 correct?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: That's what it says.</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q Meaning that there is nearly a 25</p> <p>18 percent increased risk of harm, correct?</p> <p>19 MR. LOCKE: Objection.</p> <p>20 THE WITNESS: Well, there's a confidence</p> <p>21 interval with that, but that's a -- that's what</p> <p>22 the odds ratio is.</p> <p>23 BY MR. GOLOMB:</p> <p>24 Q Right. And do you have enough</p> <p>25 experience in epidemiology to understand that that</p>	<p style="text-align: right;">Page 694</p> <p>1 BY MR. GOLOMB:</p> <p>2 Q Now, just to refresh your recollection</p> <p>3 before you -- and I'll give you whatever time you</p> <p>4 need -- when we were talking before about the PDQ,</p> <p>5 I also referred to the snapshot. Do you recall</p> <p>6 that?</p> <p>7 A Yes.</p> <p>8 Q And so this is a Snapshot of Ovarian</p> <p>9 Cancer from the NCI website. Do you understand</p> <p>10 that?</p> <p>11 MR. LOCKE: Objection. Beyond the</p> <p>12 scope, lack of foundation, form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q And that's dated August 8th, 2016,</p> <p>16 correct?</p> <p>17 MR. LOCKE: Same objections.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q Have you -- have you seen this document</p> <p>21 before?</p> <p>22 A Again, I -- well, I think I've seen</p> <p>23 something from NCI once upon a time. It would</p> <p>24 be -- I don't know what the date would be, so my</p> <p>25 answer's going to be no.</p>
<p style="text-align: right;">Page 693</p> <p>1 is statistically significant?</p> <p>2 MR. LOCKE: Objection. Beyond the</p> <p>3 scope.</p> <p>4 THE WITNESS: I think it depends --</p> <p>5 MR. LOCKE: Calls for expert testimony.</p> <p>6 THE WITNESS: Yeah, it depends on what</p> <p>7 study you're looking at. And I -- I'm surprised</p> <p>8 that they say "based on solid evidence," because</p> <p>9 that was -- this finding was specifically based on</p> <p>10 limited evidence was the conclusion.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q Well, the National Cancer Institute</p> <p>13 wrote "based on solid evidence," correct?</p> <p>14 A Yes.</p> <p>15 Q And you've never seen this before,</p> <p>16 correct?</p> <p>17 A Yes.</p> <p>18 Q So you don't know what the National</p> <p>19 Cancer Institute is basing their -- their</p> <p>20 conclusion that it's based on solid evidence?</p> <p>21 A Yeah. Actually, you're right. I was</p> <p>22 looking at the IARC sentence.</p> <p>23 Q Okay. Let's go to P-437.</p> <p>24 (Exhibit No. 77 was marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 695</p> <p>1 Q Okay. And --</p> <p>2 MR. LOCKE: I also want to note this is</p> <p>3 just one of six pages.</p> <p>4 MR. GOLOMB: Right. And this is the</p> <p>5 page that refers to talc.</p> <p>6 BY MR. GOLOMB:</p> <p>7 Q Do you see in the lower half portion of</p> <p>8 that page, the Snapshot of Ovarian Cancer, under</p> <p>9 Incidence and Mortality, it has risk factors for</p> <p>10 ovarian cancer. Do you see that?</p> <p>11 A Yes.</p> <p>12 Q And if you go down to the fourth line,</p> <p>13 do you see it says there "The use of talc"?</p> <p>14 A Yes.</p> <p>15 Q So as of August 8, 2016, on the Snapshot</p> <p>16 of Ovarian Cancer, the NCI website tells people</p> <p>17 that the use of talc is a risk factor, correct?</p> <p>18 MS. FRAZIER: Objection to form.</p> <p>19 MR. LOCKE: Objection.</p> <p>20 BY MR. GOLOMB:</p> <p>21 Q For ovarian cancer.</p> <p>22 MR. LOCKE: Lack of scope -- or beyond</p> <p>23 the scope, lack of foundation, form.</p> <p>24 THE WITNESS: This says risk factor for</p> <p>25 ovarian cancer, and it includes in their list use</p>

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<p style="text-align: right;">Page 696</p> <p>1 of talc.</p> <p>2 MR. GOLOMB: Okay. Can we go to the</p> <p>3 next document, please.</p> <p>4 BY MR. GOLOMB:</p> <p>5 Q And just for the record, this is a</p> <p>6 document which previously was marked for</p> <p>7 identification as P-645.</p> <p>8 (Exhibit No. 78 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q So this is another shot of the</p> <p>12 website -- of the NCI website, A Snapshot of</p> <p>13 Ovarian Cancer. Correct?</p> <p>14 A Yes.</p> <p>15 Q And if you look at the bottom of the</p> <p>16 page, it's dated October 14th, 2016, correct?</p> <p>17 A Yes.</p> <p>18 Q And if you look at the third full</p> <p>19 paragraph, again it identifies the use of talc as</p> <p>20 a risk factor, correct?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Yes.</p> <p>23 MR. LOCKE: Lack of foundation, scope,</p> <p>24 form, and it's one page of six.</p> <p>25 MS. FRAZIER: Join.</p>	<p style="text-align: right;">Page 698</p> <p>1 heard that, that any of those other risk factors</p> <p>2 are in dispute?</p> <p>3 MR. LOCKE: Objection. Beyond the</p> <p>4 scope.</p> <p>5 THE WITNESS: No. I -- I've never heard</p> <p>6 of tall height before, but that's just me.</p> <p>7 BY MR. GOLOMB:</p> <p>8 Q But at least of -- again, this is dated</p> <p>9 December 13th, 2017, on the Snapshot of Ovarian</p> <p>10 Cancer, the NCI identifies the use of talc as a</p> <p>11 risk factor, correct?</p> <p>12 MR. LOCKE: Same objection.</p> <p>13 MR. DUFFY: Beyond the scope.</p> <p>14 MS. FRAZIER: Same objection.</p> <p>15 THE WITNESS: That's what it says.</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q And so if I understand your -- your</p> <p>18 testimony correctly, you have never seen any of</p> <p>19 these PDQs before, correct?</p> <p>20 A I think at some point I probably saw a</p> <p>21 PDQ. I can't remember when or -- or what. Again,</p> <p>22 we -- we didn't have any contact at all with NCI</p> <p>23 or any connection, but I know I heard about it at</p> <p>24 some point.</p> <p>25 Q Okay. And -- and did you -- did you</p>
<p style="text-align: right;">Page 697</p> <p>1 BY MR. GOLOMB:</p> <p>2 Q Okay. Let's go to the next document.</p> <p>3 MR. GOLOMB: What's the number of this?</p> <p>4 MR. LOCKE: 79.</p> <p>5 BY MR. GOLOMB:</p> <p>6 Q Okay. This is Exhibit 79.</p> <p>7 (Exhibit No. 79 was marked for</p> <p>8 identification.)</p> <p>9 BY MR. GOLOMB:</p> <p>10 Q Again, this is another Snapshot of</p> <p>11 Ovarian Cancer, which -- in which it continues to</p> <p>12 identify the use of talc as a risk factor,</p> <p>13 correct?</p> <p>14 A Along with --</p> <p>15 MR. LOCKE: Objection. Same as before,</p> <p>16 lack of foundation, form, beyond the scope, and</p> <p>17 it's one page of six.</p> <p>18 MS. FRAZIER: Join.</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q Correct?</p> <p>21 A Along with many other factors, yes.</p> <p>22 Q Okay. But the use of talc is a factor?</p> <p>23 A It is listed there.</p> <p>24 Q Okay. So I don't think anybody is</p> <p>25 disputing any of the other risk factors. Have you</p>	<p style="text-align: right;">Page 699</p> <p>1 learn at some point that after December 13th,</p> <p>2 2017, that the NCI took the use of talc off of its</p> <p>3 website?</p> <p>4 A I couldn't have told you what the date</p> <p>5 was, but at some point I did learn that it was not</p> <p>6 listed there.</p> <p>7 Q And how did you learn that?</p> <p>8 A I have no recall. Again, we didn't -- I</p> <p>9 mean, someone must have mentioned it to me at some</p> <p>10 point or -- yeah, I don't know.</p> <p>11 Q Okay. And did you learn about -- did</p> <p>12 you know about its proximity to one of the trials</p> <p>13 in this case?</p> <p>14 A No.</p> <p>15 Q Okay. So until I -- I'm telling you</p> <p>16 now, you were unaware that the NCI took the use of</p> <p>17 talc off of its website just days before a trial</p> <p>18 in one of these cases?</p> <p>19 MR. LOCKE: Objection.</p> <p>20 MS. FRAZIER: Object to form.</p> <p>21 MR. LOCKE: Beyond the scope.</p> <p>22 And just for the record, PCPC wasn't a</p> <p>23 defendant in that trial.</p> <p>24 THE WITNESS: No, I did not know that.</p> <p>25 BY MR. GOLOMB:</p>

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<p>1 Q Okay. So as you sit here today, you</p> <p>2 recall that the NCI removed it from its website.</p> <p>3 You don't remember how you -- how you learned</p> <p>4 that, and you don't know how that got off the</p> <p>5 website. Is that your testimony?</p> <p>6 A Correct.</p> <p>7 Q Okay. Let's talk about the Talc</p> <p>8 Interested Party Task Force. And I -- we've</p> <p>9 talked a lot about this in the last deposition,</p> <p>10 and so I'm going to try not to repeat myself.</p> <p>11 But to be clear, there are various</p> <p>12 records, some of which -- most of which refer to</p> <p>13 the Talc Interested Party Task Force, some of</p> <p>14 which refer to the Interested Party Task Force.</p> <p>15 They're one and the same; is that correct?</p> <p>16 A That's correct.</p> <p>17 Q Do you know when the task force was</p> <p>18 created?</p> <p>19 A I believe it was created in 19 -- maybe</p> <p>20 '71, or early '70s.</p> <p>21 Q And why was it created?</p> <p>22 A In response to the finding of asbestos</p> <p>23 or the reporting of asbestos in talc.</p> <p>24 Q Okay. Well, was it the reporting of</p> <p>25 asbestos or was it the reporting of talc in the</p>	<p>1 reports, and I know there was some question as to</p> <p>2 what was actually found, but there were reports, I</p> <p>3 believe in the newspaper, from findings out of --</p> <p>4 I think it was Mount Sinai Hospital or -- anyway,</p> <p>5 of the finding of asbestos in talc.</p> <p>6 Q And that was -- was that the finding of</p> <p>7 asbestos in talc, that talc specifically being</p> <p>8 found in the ovarian tissue?</p> <p>9 A No. I thought it was just talc being</p> <p>10 found in -- excuse me -- asbestos being found in</p> <p>11 talcum products.</p> <p>12 Q Just generally?</p> <p>13 A Yes.</p> <p>14 Q All right. And so you don't have a</p> <p>15 recollection one way or the other as to what the</p> <p>16 Henderson study concluded?</p> <p>17 A My recollection of the Henderson study</p> <p>18 is that they were reporting the finding of talc in</p> <p>19 ovaries, but I believe they also found them in</p> <p>20 controlled women that hadn't been exposed to talc.</p> <p>21 So it was --</p> <p>22 Q Okay. And as you sit here today, do you</p> <p>23 know one way or the other as to whether or not</p> <p>24 the -- the Talc Interested Party Task Force was</p> <p>25 created before or after the Henderson study?</p>
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<p>1 ovarian tissue?</p> <p>2 A I thought it was the reporting of</p> <p>3 asbestos.</p> <p>4 Q All right. You -- you were asked</p> <p>5 earlier by Mr. Tisi about the association between</p> <p>6 talc and ovarian cancer, and I think -- correct me</p> <p>7 if I'm wrong, I think you said that you -- that</p> <p>8 "you," meaning PCPC, CFTA -- first learned about</p> <p>9 that potential association in 1982 after the</p> <p>10 Cramer study. Was that your testimony?</p> <p>11 A I believe that's correct, yes.</p> <p>12 Q Are you familiar with the Henderson</p> <p>13 study?</p> <p>14 A I do know what you are talking about,</p> <p>15 yes.</p> <p>16 Q And that was in the early '70s, correct?</p> <p>17 A That sounds right.</p> <p>18 Q All right. Was the Talc Interested</p> <p>19 Party Task Force formed in response to the</p> <p>20 Henderson study?</p> <p>21 A I believe it was formed in response to</p> <p>22 the asbestos finding.</p> <p>23 Q All right. And when you say "asbestos</p> <p>24 finding," what are you referring to?</p> <p>25 A Well, I'm referring to the newspaper</p>	<p>1 MR. LOCKE: Objection. Asked and</p> <p>2 answered.</p> <p>3 THE WITNESS: As far as I'm aware, it</p> <p>4 was created in response to the asbestos issue.</p> <p>5 BY MR. GOLOMB:</p> <p>6 Q Okay. Well, that -- but that wasn't my</p> <p>7 question. My question was, do you know one way or</p> <p>8 the other as you sit here today -- because you</p> <p>9 don't -- you don't know the chronology of the --</p> <p>10 the asbestos finding and the Henderson study,</p> <p>11 correct?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: Yeah, I don't know the</p> <p>14 year of the Henderson study.</p> <p>15 BY MR. GOLOMB:</p> <p>16 Q Right. But my question to you is a very</p> <p>17 specific one, and that is, do you have a</p> <p>18 recollection one way or the other as to whether or</p> <p>19 not the Talc Interested Party Task Force was</p> <p>20 created in response to the Henderson study?</p> <p>21 MR. LOCKE: Objection. Asked and</p> <p>22 answered.</p> <p>23 THE WITNESS: What's the question? Was</p> <p>24 it in response --</p> <p>25 MR. GOLOMB: Can you read back the</p>

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<p>1 question, please.</p> <p>2 THE WITNESS: I believe no.</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Okay.</p> <p>5 A I believe it was created in response to</p> <p>6 the asbestos issue.</p> <p>7 Q And when you say "in response," what was</p> <p>8 the purpose of it?</p> <p>9 A To address -- when there was the</p> <p>10 finding, it was to look further into that to see</p> <p>11 if it was real, and then ultimately to come up</p> <p>12 with a specification so that -- to confirm that</p> <p>13 there was no asbestos in talc.</p> <p>14 Q And -- and how is -- how is a task force</p> <p>15 like that created?</p> <p>16 A So in general, if you -- I mean, if</p> <p>17 there's a finding, then basically we inform our</p> <p>18 members, and we look for interest in pursuing some</p> <p>19 activities related to a -- a particular issue.</p> <p>20 And in those -- those people again would, on their</p> <p>21 own then, that would be the group that would</p> <p>22 decide where do we go from here, what do we do.</p> <p>23 Q Okay. So it comes from you, meaning the</p> <p>24 PCPC, rather than the members coming to you and</p> <p>25 saying, you know, I just read something, this may</p>	<p>1 could where we think we might have members who are</p> <p>2 interested, should know about this, and then see</p> <p>3 if they're interested in again, you know, taking</p> <p>4 on further activities related to a particular</p> <p>5 topic.</p> <p>6 Q And when you say "further activities,"</p> <p>7 what kind of activities?</p> <p>8 A It totally depends on what the task</p> <p>9 force is. Like I say, in the case of the talc-</p> <p>10 asbestos issues, then it was putting together a</p> <p>11 specification -- or, rather, there was a talc</p> <p>12 specification, but adding in asbestos -- asbestos</p> <p>13 to that specification and working on methods to --</p> <p>14 for protection.</p> <p>15 Q And one of the, as you say, further</p> <p>16 activities is the hiring of scientists, correct?</p> <p>17 A Well, it could be.</p> <p>18 Q Right. And it was in the case of the</p> <p>19 talc -- the talc task force, correct?</p> <p>20 A I'm not sure what you mean by "hiring of</p> <p>21 scientists."</p> <p>22 Q Well, at some point in time in the -- in</p> <p>23 response to the Citizens Petition, in response to</p> <p>24 the NTP preliminary findings, the members of the</p> <p>25 PCPC at that time, the CFTA, who were also a</p>
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<p>1 be something that we need to create a task force</p> <p>2 for?</p> <p>3 A Oh, no, it depends. It can go either</p> <p>4 way. It can be us finding something. It's</p> <p>5 basically -- what our role would be then to</p> <p>6 disseminate that information to see if there is</p> <p>7 interest in forming a task force and -- and taking</p> <p>8 on further activities.</p> <p>9 Q Okay. And in the case of the Talc</p> <p>10 Interested Party Task Force, was that something</p> <p>11 where the -- the CFTA went through its members or</p> <p>12 one of its members came to the CFTA?</p> <p>13 A I think I'd have to say I don't know.</p> <p>14 Q Did you go back and -- there's minutes</p> <p>15 of these -- of these meetings, right?</p> <p>16 A Yes.</p> <p>17 Q So let me ask you generally, when the</p> <p>18 idea is created to -- to create a task force, how</p> <p>19 is it then implemented?</p> <p>20 A We would go out to -- in general, and</p> <p>21 this is -- since this was years before, it's going</p> <p>22 to be a little bit of a different setup that I'm</p> <p>23 not going to be aware of, but we would go out to</p> <p>24 committees where we think there might be interest,</p> <p>25 we would try to spread the word as widely as we</p>	<p>1 member of the Talc Interested Party Task Force,</p> <p>2 funded the hiring of scientists and experts to</p> <p>3 defend them in front of the NTP and to respond to</p> <p>4 the -- to the Citizens Petition, correct?</p> <p>5 A That can be one of the activities that</p> <p>6 we undertake, yes.</p> <p>7 Q But it's --</p> <p>8 A It can be doing a study, it could be</p> <p>9 hiring a scientist or hiring a consultant, I</p> <p>10 guess, to look at an issue.</p> <p>11 Q Okay.</p> <p>12 A It could be any number of things.</p> <p>13 Q Okay. And -- and I think we can agree</p> <p>14 that the -- the funding of the -- these task</p> <p>15 force, and the talc task force in particular, is</p> <p>16 not your bailiwick, so to speak, correct?</p> <p>17 A Yes. I mean -- I mean, I could speak</p> <p>18 generally to funding of task forces. I mean,</p> <p>19 obviously depending on how much funding is</p> <p>20 available and where people's level of interest in</p> <p>21 helps define what your future activities are.</p> <p>22 Q No, but I -- I understand that. But my</p> <p>23 question is, if I were to ask you specific</p> <p>24 questions about the funding of the talc task</p> <p>25 force, that is not your bailiwick.</p>

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<p>1 A That was Mark Pollack.</p> <p>2 Q Right. And so were you -- were you ever</p> <p>3 shown the -- the chart that Mr. Pollack created</p> <p>4 for us where -- for this litigation which</p> <p>5 identifies how much was deposited into the account</p> <p>6 of the Talc Interested Party Task Force over the</p> <p>7 years?</p> <p>8 A I think I've seen that, yes.</p> <p>9 Q Okay. And so that was somewhere close</p> <p>10 to half a million dollars, correct?</p> <p>11 A I mean that -- that sounds about right.</p> <p>12 Q And about 67 percent of that was funded</p> <p>13 specifically by J&J and Imerys and the</p> <p>14 predecessors of Imerys, correct?</p> <p>15 A That's what I heard this morning, yes,</p> <p>16 and that sounds right, consistent.</p> <p>17 Q And I think you said something -- that</p> <p>18 there were something like 18 or 20 different</p> <p>19 members of the task force.</p> <p>20 A I'm not sure there's -- I don't think</p> <p>21 there was more than that, but there was probably</p> <p>22 close to that. Fifteen.</p> <p>23 Q All right. And so the other 16 or so</p> <p>24 members of the task force put up a third of the</p> <p>25 funding, and Imerys and J&J put up the balance?</p>	<p>1 Q Well, as you -- as you said in your --</p> <p>2 your testimony just earlier today, the -- you see</p> <p>3 this -- whether it was the Henderson study or what</p> <p>4 you said was that asbestos was found in the talc,</p> <p>5 that the -- the CFTA then went to its members to</p> <p>6 determine the level of interest for a task force,</p> <p>7 correct?</p> <p>8 A I said that --</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: Yeah, I said that's how</p> <p>11 generally it works. I mean, I'm not sure exactly</p> <p>12 how that happened. But, yes, we -- we would want</p> <p>13 to inform our members, because that's one of the</p> <p>14 things we do, inform them what issues might be</p> <p>15 related to them, and then we would generally</p> <p>16 spread the word, is there interest, is there</p> <p>17 something that, you know, we should form a task</p> <p>18 force for. So I assume that's the way it went</p> <p>19 there basically.</p> <p>20 BY MR. GOLOMB:</p> <p>21 Q And people you think may be interested</p> <p>22 are then in some form or fashion contacted?</p> <p>23 A Well, we would contact -- now -- now</p> <p>24 certainly -- again, things were a little different</p> <p>25 back then, but now we would contact through our</p>
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<p>1 A That -- that could be.</p> <p>2 Q Okay. And once the task force is -- is</p> <p>3 created, what happens next?</p> <p>4 A Well, I mean, then they would get</p> <p>5 together and talk about it, and what activities do</p> <p>6 we undertake, what do we understand about this,</p> <p>7 what questions, is there -- you know, what</p> <p>8 follow-up is needed to understand what the issue</p> <p>9 is, and where do we go from here. And then if it</p> <p>10 comes to things that cost money, then it was like</p> <p>11 going out and getting proposals or -- and seeing</p> <p>12 what people want to do.</p> <p>13 Q Okay. And what happened in this case,</p> <p>14 in the case of the Talc Interested Party Task</p> <p>15 Force? When -- when was it first discussed</p> <p>16 amongst its members?</p> <p>17 A Are you talking about 1971 when it was</p> <p>18 first formed?</p> <p>19 Q Well, if that's when it was.</p> <p>20 A I mean, then there were discussions</p> <p>21 ongoing about asbestos, and we need methodologies</p> <p>22 so we can detect if there's asbestos in talc,</p> <p>23 and -- and there was a great deal of activity</p> <p>24 related to that, which included FDA activities as</p> <p>25 well.</p>	<p>1 committees. We have a Safety and Regulatory</p> <p>2 Toxicology Committee. It's a very large committee</p> <p>3 with a very large mailing list, so that gets to a</p> <p>4 lot of people. We have a Scientific Advisory</p> <p>5 Executive Committee now, it now has a different</p> <p>6 name, but -- and again, there would be more people</p> <p>7 we would contact. So we would make sure we spread</p> <p>8 the word because we're just trying to make sure</p> <p>9 everybody knows what's going on and see if they</p> <p>10 have interest.</p> <p>11 Q And then at some point, whether it's</p> <p>12 1971 or the way you do it now, once you assess</p> <p>13 those responses, you have a meeting of some sort,</p> <p>14 whether it's in person or telephone. Correct?</p> <p>15 A Generally, right, we -- then once we had</p> <p>16 identified interested people, then we would want</p> <p>17 to get that group together.</p> <p>18 Q Okay. And then the -- those interested</p> <p>19 parties are identified, some employees of the CFTA</p> <p>20 at the time are then kind of the ones in charge of</p> <p>21 having that liaison with the members on that</p> <p>22 particular task force, correct?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: Yes. Somebody -- somebody</p> <p>25 would -- from the association would be involved.</p>

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<p style="text-align: right;">Page 712</p> <p>1 BY MR. GOLOMB:</p> <p>2 Q Okay. And when this -- when this task</p> <p>3 force was first created, who was that person from</p> <p>4 the CFTA?</p> <p>5 A I believe it was -- at the time I think</p> <p>6 we only had one science person, so it was Norm</p> <p>7 Estrin.</p> <p>8 Q I'm sorry?</p> <p>9 A Norm Estrin, I believe.</p> <p>10 Q And then there was -- there was in some</p> <p>11 form or fashion a meeting held of the prospective</p> <p>12 interested parties?</p> <p>13 A Yes. I mean, I looked at a lot -- a lot</p> <p>14 of minutes and there were a lot of meetings held.</p> <p>15 Q Okay. Did you see minutes from the --</p> <p>16 from back -- dating back to 1971?</p> <p>17 A I don't know about '71.</p> <p>18 Q Well, when was the first --</p> <p>19 A I saw them back to the '70s.</p> <p>20 Q Okay. Because I'll represent to you</p> <p>21 that the first meeting minutes that we have which</p> <p>22 refers to the, quote, ad hoc talc task force is</p> <p>23 1982.</p> <p>24 Were there minutes before that?</p> <p>25 A I know I saw documents relating to</p>	<p style="text-align: right;">Page 714</p> <p>1 Q Okay. I'm showing you Exhibit 80, which</p> <p>2 is the cover page of those minutes.</p> <p>3 Take -- take whatever time you need just</p> <p>4 to read that.</p> <p>5 A (Peruses document.) Okay.</p> <p>6 Q Okay. Now, when you have a -- a task</p> <p>7 force like this, is somebody appointed as a -- as</p> <p>8 a chairman of sorts of the committee?</p> <p>9 A It depends. Sometimes yes, sometimes</p> <p>10 no.</p> <p>11 Q What does it depend on?</p> <p>12 A The nature of the committee, the people</p> <p>13 who are on it.</p> <p>14 Q Okay. And do you recall in -- in this</p> <p>15 particular case whether or not a chairman was</p> <p>16 nominated and then agreed to?</p> <p>17 A You know, I recall in the case of going</p> <p>18 back to the '70s when the specifications was going</p> <p>19 on, I think there was a chair for that effort</p> <p>20 around developing methodology. I think there was</p> <p>21 also a chair on kind of the more overarching talc,</p> <p>22 not the -- I know I'm not answering your question.</p> <p>23 I'm just trying to think here.</p> <p>24 Do I recall if there was one here? I</p> <p>25 guess I'd have to say I don't recall.</p>
<p style="text-align: right;">Page 713</p> <p>1 working on specifications. I thought they were</p> <p>2 minutes. Maybe I'm wrong, but I know I saw</p> <p>3 documents relating to that.</p> <p>4 Q Okay. And the date of the first task</p> <p>5 force minutes, which I'll show you in a minute,</p> <p>6 are dated November 11th, 1982. Do you recall</p> <p>7 seeing minutes from November 11th, 1982?</p> <p>8 A I wouldn't recall a precise date. I</p> <p>9 know that there were minutes going into the '80s,</p> <p>10 and that would have been after the Cramer study.</p> <p>11 So...</p> <p>12 Q Right. And that's -- that was my next</p> <p>13 question. That is a date which coincides shortly</p> <p>14 after the Cramer study.</p> <p>15 A Okay.</p> <p>16 Q So is that consistent with your</p> <p>17 recollection that there was minutes of the ad hoc</p> <p>18 talc task force shortly after the Cramer study was</p> <p>19 published?</p> <p>20 A I know that there was definitely -- that</p> <p>21 the task force got together after the Cramer study</p> <p>22 was published, yes.</p> <p>23 (Exhibit No. 80 was marked for</p> <p>24 identification.)</p> <p>25 BY MR. GOLOMB:</p>	<p style="text-align: right;">Page 715</p> <p>1 Q Okay. Is it -- is it consistent with</p> <p>2 your recollection that there was maybe some</p> <p>3 activity surrounding the asbestos issue in 1971,</p> <p>4 and then no longer activity until 1982, when the</p> <p>5 Cramer study came out?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: No, there was activity in</p> <p>8 the '70s relating to the asbestos and development</p> <p>9 of -- of methodology that went well into the '70s.</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q Okay. And would there have been various</p> <p>12 meetings in the '70s, whether they were by</p> <p>13 telephone or in person?</p> <p>14 A I believe that's correct, yes.</p> <p>15 Q And are -- whether the meeting is held</p> <p>16 by telephone or in person, are there minutes of</p> <p>17 those meetings?</p> <p>18 A Again, I'm -- I mean, I've seen things</p> <p>19 on developments of them. Were they minutes or</p> <p>20 were they otherwise memos? Off the top, I don't</p> <p>21 know. I thought they were minutes. I could be</p> <p>22 wrong.</p> <p>23 Q Okay. And was a -- was a chairman of</p> <p>24 this particular committee appointed before</p> <p>25 November 11th, 1982?</p>

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<p>1 A Well, if there's a chairman appointed on 2 the asbestos -- on the earlier work, that doesn't 3 mean that would be the same chairman in 1982. 4 Q Okay. And do you know who Dr. Bruce 5 Semple is? 6 A I think I've heard the name. He's at -- 7 I want to say P&G. 8 Q I'm sorry? 9 A I want to say Procter & Gamble, but I 10 could be wrong. 11 Q Okay. Well -- 12 A Only because I've seen the name. I 13 don't believe I've met the person because that 14 would have been too long ago. 15 Q If I told you there's a document that 16 says: "On November 11, 1982, nominations were 17 taken from the committee to elect a chairman. 18 After discussion, the task force agreed to elect a 19 chairman and a vice-chairman. Dr. Bruce Semple 20 from Johnson & Johnson was unanimously elected 21 chairman. Dr. Edward Jackson from Knoxville was 22 unanimously elected vice-chairman." 23 Would that refresh your recollection? 24 MR. LOCKE: Objection. Let the record 25 reflect that counsel is reading from pages that</p>	<p>1 A Yes. 2 Q All right. And you -- you told us 3 earlier that you read the various minutes of this 4 committee to prepare for your deposition, correct? 5 A I read some minutes from this committee, 6 yes, or this task force. 7 Q All right. And generally -- I'm sorry? 8 A Task force, I guess we call it. 9 Q Right. And generally, what was the goal 10 of the task force back in November of 1982? 11 A Well, I think just from the minutes, it 12 was -- the concern was the ovarian cancer issue, 13 just given that the study had come out, the Cramer 14 study. And I know in minutes I've seen, and this 15 refers to them, a thought of doing a study to look 16 at translocation. So I think that was certainly 17 one of the big discussion points. 18 Q Okay. And when you say "look at 19 translocation," what do you mean? 20 A Trans -- talc can translocate from the 21 perineum to the ovary. 22 Q Okay. And what was -- what was done by 23 the CFTA back in 1982 in conjunction with the task 24 force to address that issue? 25 A So there were -- I think it was actually</p>
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<p>1 have not been shown to the witness, probably of 2 the very same minutes that we're seeing the cover 3 page of. 4 BY MR. GOLOMB: 5 Q I will refer you to page 2, subsection 4 6 under Administrative Chairman, and take a look at 7 that and tell me if I read that accurately. 8 A Yes, you read it accurately. 9 Q Thank you. 10 Who is H. Joseph Sekerke, Ph.D.? 11 A He is a -- was a CTFA employee 12 scientist. 13 Q Okay. So would he have been that person 14 that liaison that we discussed earlier of this 15 particular committee in 1982? 16 A I think that would be likely. 17 Q Okay. And that's who these minutes were 18 signed by -- he just writes "Joe," Joe Sekerke. 19 A It makes sense. I mean, it -- again, 20 the science staff was very small at that point, so 21 that was up from one to two at least. So that 22 makes sense. 23 Q Okay. And you mentioned that in -- in 24 1982, we agree that Dr. Semple was the chairman of 25 this committee, correct?</p>	<p>1 two studies, although I think one was kind of a 2 beginner study leading to a bigger study with 3 monkeys using radio tracers, I think three 4 different radio tracers, that was implanted in the 5 monkey vaginas, and it was -- then it was assessed 6 whether they could -- the talc would translocate 7 to the ovary. 8 Q Okay. And then what was done next by 9 the task force or any of its members? 10 A I -- I don't know what you mean. 11 Q Well, do you know one way or the other 12 as to whether or not any of the members were then 13 sent out to go talk to Dr. Cramer about his -- his 14 paper? 15 A I'm not sure. If you can show me 16 documents that can refresh my memory. 17 Q Well, I'm just asking you, based on your 18 understanding as you sit here today whether or not 19 Dr. Semple went to go talk to Dr. Cramer? 20 A I don't remember. I mean, I may well 21 have looked at those documents. I just don't 22 remember. 23 Q Okay. And what else in the 1980s did 24 the task force do? 25 A 1980s -- sorry. I just need to think.</p>

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<p style="text-align: right;">Page 720</p> <p>1 I -- I don't remember. I mean, I know</p> <p>2 that was the big study that was done.</p> <p>3 Q I'm sorry.</p> <p>4 A That was the big study that was done.</p> <p>5 Again, if you show me documents to refresh my</p> <p>6 memory, that would be --</p> <p>7 Q All right. And is it fair to say that</p> <p>8 whether it's the -- the Talc Interested Party Task</p> <p>9 Force or any other task force, that they don't</p> <p>10 necessarily meet on a regular basis, but they meet</p> <p>11 kind of depending on the activity of the -- that</p> <p>12 would be interesting -- interested to the task</p> <p>13 force?</p> <p>14 A That is correct, particularly with the</p> <p>15 task force. We have some standing committees that</p> <p>16 meet regularly, but task force, almost by</p> <p>17 definition, are responding to specific issues.</p> <p>18 Q Okay. So do you know one way or on the</p> <p>19 other as to whether or not there was a meeting of</p> <p>20 the task force between November 11th, 1982, and</p> <p>21 September 16th of 1993, which I'll represent to</p> <p>22 you is the -- I'm sorry -- February 2nd, 1993,</p> <p>23 which is -- I'll represent to you is the -- the</p> <p>24 next minutes that we have?</p> <p>25 MR. LOCKE: Objection.</p>	<p style="text-align: right;">Page 722</p> <p>1 his paper was circulated to the members of the</p> <p>2 task force before it was published?</p> <p>3 A I believe it was.</p> <p>4 Q Okay. And is it -- is it your -- your</p> <p>5 experience that that is a -- is an ethical</p> <p>6 approach to the publication of a paper, to</p> <p>7 circulate it to people who have a financial</p> <p>8 interest in the outcome of the paper before it's</p> <p>9 published in a scientific journal?</p> <p>10 MR. LOCKE: Objection to form and beyond</p> <p>11 the scope.</p> <p>12 THE WITNESS: What -- what we -- the</p> <p>13 comments that we're looking for are typos,</p> <p>14 clarity. We can't question the conclusion of the</p> <p>15 authors, and when we're hiring ethical people,</p> <p>16 they're not going to let us do that.</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q Okay. So then -- so you have -- you --</p> <p>19 the task force meets. They agree on an approach,</p> <p>20 in this case the approach is to -- is to contact</p> <p>21 and retain Dr. Gross, give Dr. Gross kind of his</p> <p>22 marching orders of what he is going to do. He</p> <p>23 goes out and does it. The -- the money is then</p> <p>24 funded by the task force comes from your</p> <p>25 organization. It's then circulated, and you meet</p>
<p style="text-align: right;">Page 721</p> <p>1 THE WITNESS: I -- I don't know.</p> <p>2 BY MR. GOLOMB:</p> <p>3 Q All right. Do you know, based on your</p> <p>4 recollection of your preparation for this</p> <p>5 deposition, as to whether or not there was</p> <p>6 something that was going on between 1982 and 1992</p> <p>7 that would have interested the task force?</p> <p>8 A I mean, I think -- I think there were</p> <p>9 papers that were looked at, but I couldn't be more</p> <p>10 specific than that at this point. Again --</p> <p>11 Q Papers looked at by whom?</p> <p>12 A I think there may have been ovarian</p> <p>13 cancer papers that were looked at. But again, if</p> <p>14 you can show me something to -- to help my memory,</p> <p>15 that would be great, but -- I know there were big</p> <p>16 things going on in '93, but --</p> <p>17 Q Okay. And then as -- as you were</p> <p>18 questioned earlier today by Mr. Tisi, Dr. Gross</p> <p>19 was then hired in 1993, correct?</p> <p>20 A Was that '93? Yes.</p> <p>21 Q All right. And that's when he -- he</p> <p>22 published his meta-analysis, correct?</p> <p>23 A Yes.</p> <p>24 Q And do you know one way or the other as</p> <p>25 to whether or not Dr. Gross's paper or draft of</p>	<p style="text-align: right;">Page 723</p> <p>1 to discuss the -- the -- what potential</p> <p>2 typographical errors. Is that your testimony?</p> <p>3 MR. LOCKE: Objection to form.</p> <p>4 THE WITNESS: No, that wasn't my</p> <p>5 testimony. I guess it would just be helpful if I</p> <p>6 could see the documents.</p> <p>7 I mean, we -- when we -- when we hire a</p> <p>8 consultant, yes, we do look at -- and there are</p> <p>9 areas that we have -- industry has knowledge that</p> <p>10 a consultant may not. We're hiring -- for</p> <p>11 example, if we're hiring somebody who is an expert</p> <p>12 epidemiologist, we can't question his epi- --</p> <p>13 their epidemiology findings, but we may have more</p> <p>14 knowledge about how talc is used by a consumer,</p> <p>15 how -- you know, questions about analysis of talc,</p> <p>16 purity of talc, mining, mineralogy.</p> <p>17 So we're reviewing it as -- with some</p> <p>18 expertise, and as well as saying, you know, if we</p> <p>19 get a document back and we think there could be</p> <p>20 more clarity, I mean, I think it's okay to say to</p> <p>21 an author, Could you clarify a little more what</p> <p>22 you mean here.</p> <p>23 BY MR. GOLOMB:</p> <p>24 Q Well, does the -- does the document --</p> <p>25 once the -- once the draft from the outside expert</p>

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<p style="text-align: right;">Page 724</p> <p>1 is -- is written, does that paper then go to the</p> <p>2 CTFA or does it go to one of the members?</p> <p>3 A Typically -- typically it would go -- if</p> <p>4 CTFA is the one, or PCPC, is arranging that, then</p> <p>5 it would come back to us, and then we would</p> <p>6 distribute it to the task force.</p> <p>7 Q Okay. Have you ever seen a situation</p> <p>8 where an expert was hired and the draft went to an</p> <p>9 industry member before it went to -- to the CTFA</p> <p>10 and was circulated to its members?</p> <p>11 A Only --</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: Only the one we talked</p> <p>14 about this morning.</p> <p>15 BY MR. GOLOMB:</p> <p>16 Q Which one was that?</p> <p>17 A The Huncharek/Muscat review.</p> <p>18 Q Okay. Let me show you the next</p> <p>19 document.</p> <p>20 MR. GOLOMB: This is Exhibit 81.</p> <p>21 (Exhibit No. 81 was marked for</p> <p>22 identification.)</p> <p>23 BY MR. GOLOMB:</p> <p>24 Q And for the record, this is a memorandum</p> <p>25 dated September 22nd, 1993, from Stephen Gettings,</p>	<p style="text-align: right;">Page 726</p> <p>1 A I -- I don't know.</p> <p>2 MR. LOCKE: Objection.</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q If you just read the second paragraph,</p> <p>5 you'll see: "It has been proposed that we arrange</p> <p>6 for Dr. Gross to publish his analysis." Do you</p> <p>7 see that?</p> <p>8 A Yes.</p> <p>9 Q And then the next sentence says:</p> <p>10 "Johnson & Johnson will arrange for preparation of</p> <p>11 a first draft, which will then be reviewed by the</p> <p>12 task force." Correct?</p> <p>13 A Yes.</p> <p>14 Q Okay. Is that the first time you've</p> <p>15 ever seen anything like that where a member -- an</p> <p>16 industry member gets the first draft of -- and</p> <p>17 then they circulate it?</p> <p>18 MR. LOCKE: Objection.</p> <p>19 MS. FRAZIER: Object to form.</p> <p>20 THE WITNESS: Well, as I say, the one</p> <p>21 this morning would be the other one, but "will</p> <p>22 arrange for the preparation," so I guess they're</p> <p>23 the interface with the consultant. And then it</p> <p>24 will go to the task force. So I'm not sure if J&J</p> <p>25 is reviewing the draft. They're arranging for the</p>
<p style="text-align: right;">Page 725</p> <p>1 Ph.D., to the Talc Interested Party Task Force.</p> <p>2 First of all, let me just ask you for</p> <p>3 the record, Dr. Gettings was the director of</p> <p>4 toxicology at that time, correct?</p> <p>5 A Yes.</p> <p>6 Q And was there overlap between</p> <p>7 Dr. Gettings being the director of toxicology and</p> <p>8 the time that you came to the CTFA?</p> <p>9 A No.</p> <p>10 Q When did Dr. Gettings leave?</p> <p>11 A I -- well, I started in October of '97,</p> <p>12 and he left soon before then. He had actually</p> <p>13 moved over to the legal department and was there</p> <p>14 very briefly, and then he moved on to -- he went</p> <p>15 to a member company.</p> <p>16 Q And who replaced Dr. Gettings?</p> <p>17 A I did.</p> <p>18 Q All right. And so have you seen this</p> <p>19 document before?</p> <p>20 A I don't know. I want to say I don't</p> <p>21 think so.</p> <p>22 Q Okay. So this is a CF -- CFTA document</p> <p>23 dated September 22nd, 1993, and you did not see</p> <p>24 this in your preparation of now Day 3 of a</p> <p>25 deposition?</p>	<p style="text-align: right;">Page 727</p> <p>1 draft to be prepared is how I'm reading this.</p> <p>2 BY MR. GOLOMB:</p> <p>3 Q Okay. So that -- that's how you read</p> <p>4 "Johnson & Johnson will arrange for a preparation</p> <p>5 of a first draft"?</p> <p>6 A Probably, yeah. I don't -- I don't know</p> <p>7 for sure.</p> <p>8 Q So you don't -- as you sit here, you</p> <p>9 don't know one way or the other as to whether</p> <p>10 Johnson & Johnson received that first draft?</p> <p>11 A No.</p> <p>12 Q And if so, you don't know what happened</p> <p>13 to that first draft once it was reviewed by</p> <p>14 somebody at Johnson & Johnson and then circulated</p> <p>15 amongst the task force members, correct?</p> <p>16 MS. FRAZIER: Object to form.</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: Yeah, I don't know if J&J</p> <p>19 reviewed the draft, it went straight to the task</p> <p>20 force.</p> <p>21 BY MR. GOLOMB:</p> <p>22 Q Okay. And then it says if you -- quote</p> <p>23 in big -- in capital letters, bold: "If you DO</p> <p>24 NOT AGREE with this proposed course of action,</p> <p>25 please contact me by close of business, COB,</p>

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<p>1 Monday, September 27th, 1993." Correct?</p> <p>2 A That's what it says, yes.</p> <p>3 Q And are you aware one way or the other</p> <p>4 as to whether or not anybody objected to that?</p> <p>5 A No, I would not be aware.</p> <p>6 Q And is it generally the -- the role at</p> <p>7 the CFTA at the time that they review any document</p> <p>8 before it's published?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I would say we -- we</p> <p>11 generally review documents before they're</p> <p>12 published, yes.</p> <p>13 BY MR. GOLOMB:</p> <p>14 Q Okay. And you told us one of the</p> <p>15 reasons why you do that is to -- for grammatical</p> <p>16 errors. Why else would you -- why else would the</p> <p>17 CFTA review publications of outside experts before</p> <p>18 they're published?</p> <p>19 A I guess, again, I would just say that</p> <p>20 there may be some expertise, some -- you know,</p> <p>21 again, more knowledge of -- if somebody is writing</p> <p>22 on talc, the industry knows best how it's used.</p> <p>23 If there is any question of how it's sourced, that</p> <p>24 kind of thing, whether it came up in this</p> <p>25 document, I don't know, but there are certain</p>	<p>1 gathers in some form or fashion, or maybe there's</p> <p>2 some leadership to the group, like Dr. Semple and</p> <p>3 some others, that say, Okay, this is reasonable,</p> <p>4 go ahead, and then the -- the CTFA can you tell us</p> <p>5 a check.</p> <p>6 A We do a contract, and we would be the</p> <p>7 ones who would pay, yes.</p> <p>8 Q Okay. Have you ever seen a situation</p> <p>9 where the -- the industry member pays for it</p> <p>10 themselves?</p> <p>11 A Not in my experience, that's not how</p> <p>12 it's worked.</p> <p>13 Q Okay. And why do you do it that way?</p> <p>14 Why do you have -- why is the money deposited into</p> <p>15 the CTFA, and then a check written from the CTFA</p> <p>16 to the expert, rather than the industry member pay</p> <p>17 for it themselves?</p> <p>18 A Because it's multiple industry members.</p> <p>19 So we're -- we're putting the industry resources</p> <p>20 together, so we're the site where the money is</p> <p>21 collected, and then we write one check to the</p> <p>22 consultant.</p> <p>23 Q Okay. Let me show you the next</p> <p>24 document.</p> <p>25 This is 82.</p>
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<p>1 areas of expertise. Yeah, we're hiring them for</p> <p>2 their epidemiology expertise.</p> <p>3 Q And do you -- do you know who it is that</p> <p>4 paid for Dr. Gross's report?</p> <p>5 A I believe we did.</p> <p>6 Q When you say "we," you mean the PCPC?</p> <p>7 A I'm sorry. PCPC, yes.</p> <p>8 Q At the time CTFA?</p> <p>9 A Yes.</p> <p>10 Q And that would be out of money that is</p> <p>11 deposited into the task force account?</p> <p>12 A Yes. That would be typical.</p> <p>13 Q The PCPC or its predecessor CTFA</p> <p>14 wouldn't go out of pocket to pay for something</p> <p>15 like this, right? They would ask its members</p> <p>16 first?</p> <p>17 A The activities of the interested</p> <p>18 parties, that's what they are -- that's what</p> <p>19 "interested party" refers to, people who are</p> <p>20 willing to expend money, because you have to do</p> <p>21 that to get certain things done.</p> <p>22 Q Okay. And that so the -- the task force</p> <p>23 members agree on a course of action, in this case</p> <p>24 the course of action was to hire Dr. Gross.</p> <p>25 Dr. Gross makes a proposal. The task force then</p>	<p>1 (Exhibit No. 82 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Now, this is a letter from Dr. Alfred</p> <p>5 Wehner, correct?</p> <p>6 A Yes.</p> <p>7 Q And it says it's cc'd to M. Chudkowski,</p> <p>8 correct?</p> <p>9 A Yes.</p> <p>10 Q Who is that?</p> <p>11 A Michael Chudkowski, he's a J&J person.</p> <p>12 Q And is there a reason why Mr. Chudkowski</p> <p>13 was the sole member of the task force that was</p> <p>14 copied on a letter from Dr. Wehner to Dr. Gettings</p> <p>15 in November of 1993?</p> <p>16 A I think I need to read it first.</p> <p>17 Q Okay.</p> <p>18 A (Peruses document.)</p> <p>19 I don't know. I don't know if \$1400 was</p> <p>20 the whole amount, and this to me looks like this</p> <p>21 is not the way we normally do things. Normally,</p> <p>22 the -- as I say, we pay them for an interested</p> <p>23 party. So I don't know why in this case J&J</p> <p>24 was -- as asked being to pay.</p> <p>25 Q Okay. Let's be clear about this. Well,</p>

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<p>1 first of all, based on the letter, J&J was not 2 asked to pay, correct? J&J volunteered to pay. 3 A Right. 4 MR. LOCKE: Objection. Form. 5 BY MR. GOLOMB: 6 Q Right. So it says: "While you" -- it 7 says: "I am enclosing" -- meaning Dr. Wehner, "I 8 am enclosing Dr. Gross's invoice in the amount of 9 \$1400 for his professional services and expenses. 10 While you mentioned, and Mike Chudkowski 11 confirmed, that J&J would pay the costs for the 12 manuscript preparation, I believe it to be 13 appropriate for BEC to submit the invoice to CTFA 14 because CTFA requested the job." Correct? 15 A That's what it says. 16 Q Right. So they are -- although J&J has 17 volunteered to pay the full costs, at least of 18 that particular invoice, doctor -- Dr. Wehner is 19 suggesting that the -- that the check be cut by 20 the intermediary, CTFA, rather than coming from 21 Johnson & Johnson itself, correct? 22 MR. LOCKE: Objection. 23 THE WITNESS: He's saying he's 24 submitting the invoice to CTFA. So he felt from 25 where he sat, it should come to CTFA.</p>	<p>1 the Hankinson study is. 2 A I know that Dr. Hankinson was an author 3 on a couple of different studies. She was -- she 4 was one of the coauthors on the Gertig study, but 5 she was also a coauthor on the Houghton study. 6 Q Okay. And which study -- if there was a 7 minutes draft -- draft of the minutes from January 8 of 1994, do you know which Hankinson study it 9 would be referring to? 10 A I don't. I'm trying to think what year 11 the Gertig study, and I'm -- I'm blanking on that. 12 (Exhibit No. 83 was marked for 13 identification.) 14 BY MR. GOLOMB: 15 Q Okay. Let me show you the Talc 16 Interested Party Task Force. Now, this is -- it 17 says "Draft Minutes." I'm not sure that we have 18 the final minutes, but it says "Draft Minutes," 19 dated January 11th, 1994. 20 Have you seen this before? 21 A I -- I can't recall exactly which 22 minutes I've seen. If I read it, it might seem 23 familiar, but... 24 Q Okay. Did -- did you read what you 25 thought were all of the minutes of the task force</p>
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<p>1 BY MR. GOLOMB: 2 Q The invoice? 3 A Because then he says he expects that 4 we're going -- that CTFA is going to forward the 5 invoice to J&J. 6 Q Well, it says: "When you forward the 7 invoice to J&J, please have them pay out the check 8 to Alan Gross and send it to them directly." 9 So J&J is paying directly. 10 A That's what it says, yes. 11 Q Okay. And that's why that letter was 12 copied to Mr. Chudkowski, right, because -- 13 A Yes. 14 Q -- he is with J&J, and J&J volunteered 15 to pay. 16 A Correct. So this is not, I would say, 17 the usual way that we pay. 18 Q In fact, you've never seen it done that 19 way before or since, correct? 20 MR. LOCKE: Objection. 21 THE WITNESS: I think that's true. 22 BY MR. GOLOMB: 23 Q Do you know what the Hankinson study is? 24 A What year does it refer to? 25 Q Well, I'm just asking if you know what</p>	<p>1 to prepare for your deposition? 2 A I read a lot of them. 3 Q Okay. 4 A This is why I thought Bruce Semple was 5 from Procter & Gamble because he moved over to it. 6 I think -- I believe I did read these. 7 Q Okay. And attached to that, which is 8 Bates-stamped J&J 15618, which is the second 9 page -- well, it's the second page of this 10 exhibit. It's the third page of the full 11 document. The second page just saying 12 "Adjournment" and the signature of Steve Gettings. 13 Do you see it says "Draft" on the next 14 page? 15 A I'm sorry. Oh, yes, it says "Draft." 16 Q First of all, how were -- how were these 17 minutes created? Why -- why are there draft 18 minutes? 19 A Again, this is before my time. I can 20 tell you how we do it now, but I think it was the 21 same then, is generally someone would draft 22 minutes, and then it would go out to the group so 23 people could look, and if they said, You know, I 24 remember this a little differently, or really you 25 should -- we talked about this too, and it doesn't</p>

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<p>1 seem to be here. Just so members would have a 2 chance to -- to input so that they were accurate. 3 Q Okay. And these minutes are dated 4 January 11th, 1994. And if you look at page 2, 5 one of the topics that was discussed was ovarian 6 cancer. Do you see that? 7 A Yes. 8 Q And it refers to the recent paper by 9 Dr. Hankinson, correct? 10 A Yes. 11 Q And under paragraph 2, it says "M. 12 Chudkowski." Again, Michael Chudkowski from J&J, 13 correct? 14 A Yes. 15 Q It says: "Agreed to contact Dr. Gross 16 to discuss incorporation of the results of the 17 Hankinson study in his meta-analysis manuscript." 18 Do you see that? 19 A Yes. 20 Q So in this case you have a -- what 21 was -- what was Mr. Chudkowski's title at J&J? 22 A Oh, I don't know. 23 Q Was he -- was he an executive of some 24 sort? 25 A I don't know. I think he was a</p>	<p>1 Q Okay. And do you know in this case how 2 the Hankinson study was identified? 3 A No, I don't. 4 Q And then there was a conference -- some 5 sort of conversation or communication between the 6 CTFA and the task force members about that study, 7 correct? 8 A Yes. 9 Q And Mr. Chudkowski then agreed to 10 contact Dr. Gross, who had been hired and was in 11 the process of drafting a -- essentially a report 12 in defense of the -- the industry from the 13 Citizens Petition that was filed in 1993, correct? 14 A Yeah, I think that's right. He was 15 doing a meta-analysis. So... 16 Q Okay. And do -- are you aware one way 17 or the other as to whether or not there were any 18 other studies that were published in that 19 intervening time between the time that Dr. Gross 20 was hired and the time that he finalized this 21 report? 22 A No, I'm not. 23 Q Okay. So you don't know one way or the 24 other as to whether or not there are other 25 reports, other papers other than the Hankinson</p>
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<p>1 scientist. I remember him being on phone calls, 2 but I'm not sure I ever knew his title. 3 Q What kind of scientist was he? 4 A I just know he participated on technical 5 phone calls, so... 6 Q All right. So a member of the -- an 7 industry member of the task force saw -- how was 8 the -- first of all -- strike that. 9 How was the Hankinson study distributed 10 amongst the task force members? 11 A The fact that it says this 94TA03, 12 that's -- that was what we used to use, a system 13 we used to use. We used to mail them out, so I -- 14 that would -- in '94, I think that would probably 15 be correct, and we would number them accordingly 16 sequentially. 17 Q Okay. So it would be somebody -- just 18 so we're clear on this, somebody from the CTFA in 19 their role as whatever they do at the CTFA, would 20 see the Hankinson study, and then the Hankinson 21 study would be circulated to the members of the 22 task force? 23 A It could be that. It also could be a 24 member bringing something to our attention that we 25 would circulate.</p>	<p>1 study, which in fact confirm the association 2 between talc and ovarian cancer; is that correct? 3 MR. LOCKE: Objection. 4 THE WITNESS: There's also -- there's 5 reference here to another study as well. 6 BY MR. GOLOMB: 7 Q Okay. Do you know one way or the other 8 as to whether or not that study confirms the 9 association between talc and ovarian cancer? 10 A I do not. 11 Q Okay. Are you -- are you familiar with 12 the NTP inhalation study? 13 A Yes. 14 Q And what did the NTP inhalation study 15 conclude? 16 A It concluded that talc -- inhaled talc 17 was carcinogenic to female rats, caused lung 18 cancer. There was no evidence of carcinogenicity 19 in male or female mice, and I believe it was 20 equivocal evidence in male rats. 21 Q Okay. And anything else? 22 A That they concluded? 23 Q Yeah. 24 A Well, that was the main point, I guess. 25 Q When was the last time you reviewed the</p>

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<p style="text-align: right;">Page 740</p> <p>1 NTP inhalation study?</p> <p>2 A I didn't review the report. I reviewed</p> <p>3 assessments of it.</p> <p>4 Q And did you review Dr. Gross's</p> <p>5 assessment?</p> <p>6 A I don't believe so.</p> <p>7 Q Okay. So just we're -- so we're clear,</p> <p>8 that study was in the early '90s, correct?</p> <p>9 A Yes.</p> <p>10 Q And it -- it may or may not have -- have</p> <p>11 had an effect on Dr. Gross's ultimate conclusions,</p> <p>12 correct?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I mean, I don't recall</p> <p>15 that it did because it's not ovarian cancer.</p> <p>16 It's -- it's -- the NTP study is an inhalation,</p> <p>17 and it had to do with lung cancer and it was</p> <p>18 discussed at length at the ISRTP. So, I'm not</p> <p>19 sure that -- Dr. Gross, I believe, was doing on</p> <p>20 ovarian cancer.</p> <p>21 BY MR. GOLOMB:</p> <p>22 Q Okay. Is that something you're</p> <p>23 surmising, or is that something that you reviewed</p> <p>24 from the records?</p> <p>25 A I'm trying to remember about Dr. Gross's</p>	<p style="text-align: right;">Page 742</p> <p>1 and ovarian cancer, correct?</p> <p>2 A That's about right.</p> <p>3 Q Right. But this is a paper, the Gross</p> <p>4 paper was a paper that was where Dr. Gross was</p> <p>5 specifically retained by industry members of the</p> <p>6 CF -- CTFA. That's a little bit different than</p> <p>7 those other 30 papers, would you agree?</p> <p>8 A It is, yes.</p> <p>9 Q Okay. And so are you -- are you telling</p> <p>10 us that you looked at the Gross paper, reading it</p> <p>11 quickly with the same care that you did with the</p> <p>12 other more -- now more than 30 papers?</p> <p>13 MR. LOCKE: Objection. If you have a</p> <p>14 question about the Gross paper, ask the question.</p> <p>15 It's not a memory test. If you want to give her</p> <p>16 the paper, go ahead.</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q Can you answer my question?</p> <p>19 A Yeah, I'm happy to look at it, because</p> <p>20 again --</p> <p>21 Q Well, it's not a memory test. I'm just</p> <p>22 trying to -- my question is a very specific one</p> <p>23 about the -- not about the content of the paper</p> <p>24 but about the care in which you read the paper.</p> <p>25 MR. LOCKE: What difference does it</p>
<p style="text-align: right;">Page 741</p> <p>1 review, but those are two very separate issues,</p> <p>2 so --</p> <p>3 Q Okay. Well -- all right. Have you --</p> <p>4 you have -- prior to preparing for your</p> <p>5 deposition, did you -- did you review the Gross</p> <p>6 paper?</p> <p>7 A I reviewed -- I mean, by reviewed it --</p> <p>8 Q Read it.</p> <p>9 A Read it quickly. I mean, there were</p> <p>10 drafts, and I -- I looked at it, and I -- I'm</p> <p>11 recalling them as being ovarian cancer.</p> <p>12 Q Okay. And did you read it in</p> <p>13 preparation for your deposition?</p> <p>14 A I read it quickly.</p> <p>15 Q Okay. When you say "read it quickly,"</p> <p>16 what does that mean?</p> <p>17 A I just mean there's a ton of papers out</p> <p>18 there, and I certainly am not claiming to -- as I</p> <p>19 sit here, that I read each and every one and could</p> <p>20 recall the details of them.</p> <p>21 Q Well, there's -- there's a ton of</p> <p>22 papers, and I think we -- we've already talked</p> <p>23 about the numbers. There are now in excess of 30</p> <p>24 papers that were -- were written by -- by various</p> <p>25 scientists to look at the association between talc</p>	<p style="text-align: right;">Page 743</p> <p>1 make?</p> <p>2 MR. GOLOMB: Well, that's rhetorical.</p> <p>3 THE WITNESS: Your question --</p> <p>4 MR. GOLOMB: I'm not here to answer</p> <p>5 questions.</p> <p>6 THE WITNESS: Your question, I thought,</p> <p>7 was about NTP bioassay, which was an inhalation</p> <p>8 assay looking at where lung tumors were found.</p> <p>9 The Gross paper was about ovarian cancer. So I --</p> <p>10 I don't think it's in there, but if you want to</p> <p>11 show me the paper and -- where that was opined on</p> <p>12 as well, maybe it was. I -- I just don't</p> <p>13 remember.</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q All right. Well, you -- you said, and</p> <p>16 when I refer to "you," I'm referring to the CTFA,</p> <p>17 because you may not have been around at that</p> <p>18 point.</p> <p>19 A I wasn't.</p> <p>20 Q But the -- the draft -- in answer to</p> <p>21 Mr. Tisi's question earlier today, the draft of</p> <p>22 the -- the Gross paper was circulated amongst the</p> <p>23 industry members of the CTFA, correct?</p> <p>24 A That's correct.</p> <p>25 Q Right. And then it was reviewed by the</p>

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<p>1 CTFA members, and the CTFA members then forwarded</p> <p>2 comments. Correct?</p> <p>3 A I presume so. I didn't -- have not seen</p> <p>4 those comments.</p> <p>5 Q Okay. Let's take a look at the next</p> <p>6 exhibit.</p> <p>7 MR. LOCKE: Why don't we take a break.</p> <p>8 We've been going for an hour and --</p> <p>9 MR. GOLOMB: Sure.</p> <p>10 MR. LOCKE: -- almost 50 minutes. I</p> <p>11 think we've got about 44 minutes left.</p> <p>12 MR. GOLOMB: Okay.</p> <p>13 THE VIDEOGRAPHER: The time is 4:38 p.m.</p> <p>14 We're going off the record.</p> <p>15 (Recess.)</p> <p>16 THE VIDEOGRAPHER: The time is 4:49</p> <p>17 p.m., and we're back on the record.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q So we were -- we were talking about the</p> <p>20 NTP inhalation study. And correct me if I'm</p> <p>21 wrong, you -- you testified that they -- as far as</p> <p>22 you know, there would be no reason for that study</p> <p>23 to be included in the paper and analyzed within</p> <p>24 the paper.</p> <p>25 Am I summarizing your testimony</p>	<p>1 Q Okay. Well, we -- we've already --</p> <p>2 we've already gone through and -- and have agreed</p> <p>3 that the consultant is hired, the consultant is</p> <p>4 given marching orders on what to do, the</p> <p>5 consultant goes out and does it. The consultant</p> <p>6 then circulates the paper, whether it goes</p> <p>7 directly to an industry member, as it did in this</p> <p>8 case, or to the CTFA. It's then circulated to all</p> <p>9 the industry members, they edit it.</p> <p>10 Am I -- do I have it correct so far?</p> <p>11 MR. LOCKE: Objection to form.</p> <p>12 THE WITNESS: Well, I mean, they</p> <p>13 would -- I wouldn't say they edit it. They can</p> <p>14 comment on it, and then CTFA -- generally the CTFA</p> <p>15 liaison person or PCPC would compile comments, if</p> <p>16 that makes sense.</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q Okay. And would those comments include</p> <p>19 telling the scientists include this or don't</p> <p>20 include that?</p> <p>21 A I mean, in general, no. I mean, if they</p> <p>22 left off a -- didn't include a paper, for example,</p> <p>23 or something like that, it could be a -- you know,</p> <p>24 did you mean to exclude this paper or something</p> <p>25 like that, but I -- but in general --</p>
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<p>1 correctly?</p> <p>2 A As I recall, the --</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: The Gross paper, because</p> <p>5 it dealt with ovarian, and the -- and the NTP was</p> <p>6 inhalation lung cancer issue.</p> <p>7 BY MR. GOLOMB:</p> <p>8 Q Okay. So then I assume that there</p> <p>9 would -- then there wouldn't be any reason -- and</p> <p>10 based on what you told us before about kind of the</p> <p>11 subjects, how subjects are treated within a paper,</p> <p>12 and typographical or grammatical errors are edited</p> <p>13 or whatnot, there wouldn't be any reason for an</p> <p>14 industry member to tell the scientists what to</p> <p>15 include in the paper, would there?</p> <p>16 A You're talking about a consulting</p> <p>17 scientist?</p> <p>18 Q Yeah.</p> <p>19 A And would industry -- I mean, we would</p> <p>20 obviously up front say, This is what we want you</p> <p>21 to review.</p> <p>22 Q Right.</p> <p>23 A Or whatever -- whatever they're</p> <p>24 preparing it on. So I'm not sure what you mean by</p> <p>25 tell them --</p>	<p>1 Q What about -- what about the other --</p> <p>2 the vice versa of that, where they included a</p> <p>3 paper and would an industry member say, Huh-uh,</p> <p>4 take that one out?</p> <p>5 A Not -- I mean, not to better the</p> <p>6 results. You know, only if they included some</p> <p>7 topic that seemed really off topic. But, again,</p> <p>8 we're choosing our consultants carefully, so we</p> <p>9 don't think that's going to happen.</p> <p>10 Q Okay. But if -- but if that did happen,</p> <p>11 that would be a problem, wouldn't it?</p> <p>12 A If something were like poorly written or</p> <p>13 something, I mean, you could see where, of course,</p> <p>14 you could have a comment, but then you would have</p> <p>15 chosen your consultant wrong.</p> <p>16 Q Okay. But if -- if -- okay.</p> <p>17 And if -- but if the consultant was</p> <p>18 said -- told by an industry member, Include this</p> <p>19 but don't include that --</p> <p>20 A No.</p> <p>21 Q -- you would see an ethical problem in</p> <p>22 that if that happened?</p> <p>23 A Correct. I mean --</p> <p>24 MR. LOCKE: Objection. Beyond the</p> <p>25 scope.</p>

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<p style="text-align: right;">Page 748</p> <p>1 THE WITNESS: Right. If they're looking 2 at a topic, then they -- we would be hiring them 3 for their expertise, and they would be selecting 4 what -- what's relevant. 5 MR. GOLOMB: Okay. Can I have the next 6 document, please. 7 (Exhibit No. 84 was marked for 8 identification.) 9 BY MR. GOLOMB: 10 Q This is Exhibit 84. 11 This is a letter dated May 5th, 1994, 12 from Michael Chudkowski. Have you seen that 13 letter before? 14 A I don't think so. 15 Q So this is a letter on Johnson & Johnson 16 stationery dated May 4th, 1994, from Dr. Alan 17 Gross -- I mean to Dr. Alan Gross from -- 18 MS. FRAZIER: Do you have a copy of 19 that? 20 (A discussion was held off the record.) 21 BY MR. GOLOMB: 22 Q -- from Michael Chudkowski, manager of 23 preclinical evaluations. Do you see that? 24 A To Michael Chudkowski. 25 Q Do you see the signature line on the</p>	<p style="text-align: right;">Page 750</p> <p>1 the FDA to see the results of an animal study? 2 A Well, I think -- 3 MR. LOCKE: Same objection. 4 THE WITNESS: -- the FDA knows the 5 results of the animal study. That's not a 6 mystery. I think this is a publication, which 7 perhaps read poorly because it went over into 8 another totally different area. Nothing to do 9 with ovarian cancer, nothing to do with 10 epidemiology study. 11 BY MR. GOLOMB: 12 Q Okay. So you never talked to 13 Mr. Chudkowski about this, correct? 14 A No. 15 Q And you've never talked to Dr. Gross 16 about this? 17 A No. 18 Q So what -- you're surmising that they -- 19 he -- doctor -- Mr. Chudkowski wants to take the 20 rodent study out of the paper because it's saving 21 the FDA time -- 22 MR. LOCKE: Object -- 23 BY MR. GOLOMB: 24 Q -- because they already know about it? 25 MR. LOCKE: Objection. There's no</p>
<p style="text-align: right;">Page 749</p> <p>1 bottom of the page? 2 A Yes, I do. 3 Q Okay. So it's a letter from Chudkowski 4 to Gross, correct? 5 A Yes. 6 Q And on the second full paragraph, it 7 says: "Prior to submission, however, please 8 delete any reference to the NTP inhalation studies 9 conducted in rodents." 10 Did I read that correctly? 11 A You did. And the reason for that would 12 be this is a paper -- this is exactly what I was 13 saying, that it's on ovarian cancer and talc 14 exposure, that's humans. Apparently he included 15 an inhalation study in rodents. That's really off 16 topic. So it's probably -- it doesn't -- it's not 17 relevant to the conclusion related to ovarian 18 cancer and talc exposure. 19 Q Well, so you're -- you're saying that 20 only the clinical aspect would be relevant to, in 21 this case, the FDA who is looking at a -- at a 22 Citizens Petition rather than some animal study? 23 MR. LOCKE: Objection. Form. 24 BY MR. GOLOMB: 25 Q You don't think it would be relevant for</p>	<p style="text-align: right;">Page 751</p> <p>1 evidence that CTFA saw this at this time. 2 THE WITNESS: And I -- I mean, the Gross 3 paper is not -- I mean, it's being published in a 4 journal. I -- I -- this is why I was asking 5 because I was confused why two, so different 6 topics were in the same paper, and it sounded like 7 that was -- that it read that it would be better 8 to have a focus of your paper. 9 BY MR. GOLOMB: 10 Q Okay. So the -- but the -- but the 11 Gross paper is being sent to the FDA, and Mr. Tisi 12 went through it in great detail this morning, went 13 to the -- to the FDA to defend the industry 14 members against the Citizens Petition, which -- 15 which showed a -- which showed evidence of an 16 association between talc and ovarian cancer, 17 correct? 18 MR. LOCKE: Objection. 19 THE WITNESS: I'm not aware the Gross 20 paper went to the FDA. That was the Huncharek and 21 Muscat document. 22 BY MR. GOLOMB: 23 Q Okay. What was the purpose of the 24 Gross -- 25 A This was -- this was a publication. It</p>

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<p>1 was being published in the peer-reviewed 2 literature. 3 Q By -- by industry members? 4 A It was industry sponsored, yes. 5 Q Right. And so prior to the -- and I'm 6 reading this again: "Prior to submission, 7 however, please delete any reference to the NTP 8 inhalation study conducted in rodents." 9 That's what it says, correct? 10 A Correct. Because I think they were 11 asked to do a paper on ovarian cancer and talc 12 exposure. 13 Q Okay. And so are in vitro or in vivo 14 studies irrelevant to the analysis of the 15 association between talc and ovarian cancer? 16 A I think it's a different topic, and I 17 think -- again, I'm kind of speculating here, but 18 I think this was a paper that was focused on 19 ovarian cancer -- cancer and talc exposure. 20 Q In any event, Mr. Chudkowski, the 21 manager of preclinical evaluations from Johnson & 22 Johnson, was essentially telling Dr. Gross to 23 delete any reference to the NTP inhalation in this 24 letter, correct? 25 A Because it was a very different --</p>	<p>1 A It could mean, or it could mean -- no, 2 here it is. "Review and be prepared to discuss at 3 a meeting." 4 Q At the -- 5 A At an in-person meeting. 6 Q At the January 18th, 1995 meeting of the 7 task force, correct? 8 A Yes. 9 Q And where -- underneath where it says 10 "Requires Action," it says: "The attached draft 11 document," and that is the report from -- is that 12 -- what paper is this referring to? 13 A That's -- I would ask you that. I'm not 14 sure. 15 Q Okay. 16 A I mean, this is the earlier -- 17 Q This is 1994. 18 A Right. 19 Q This is the same time period in which we 20 were talking about Dr. Gross's paper. 21 A Right. 22 MR. LOCKE: Wait. This is 1995. 23 MR. GOLOMB: 19 -- January 11th, 1995. 24 The previous document that we just referred to was 25 1994.</p>
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<p>1 MR. LOCKE: Objection. Lack of 2 foundation, beyond the scope. 3 MS. FRAZIER: Join. 4 THE WITNESS: -- a very different type 5 of study, an animal study and an inhalation study. 6 It's very different. 7 BY MR. GOLOMB: 8 Q Let me show you what's being marked as 9 Exhibit 85. 10 (Exhibit No. 85 was marked for 11 identification.) 12 BY MR. GOLOMB: 13 Q This is a memorandum on CTFA stationery 14 dated January 11th, 1995, to the Talc Interested 15 Party Task Force from Stephen Gettings, director 16 of toxicology at the CTFA. The subject is "The 17 CTFA response to the Citizens Petition." 18 Do you see that? 19 A Yes. 20 Q And this says "Requires Action." Do you 21 see that? 22 A Yes. 23 Q And by require -- in the context of this 24 memo, "Requires Action" means review it and give 25 us back your comments. Correct?</p>	<p>1 MR. LOCKE: May 5th, 1994. 2 MR. GOLOMB: Okay. 3 BY MR. GOLOMB: 4 Q So, in any event, this says: "Subject: 5 CTFA Response to Citizens Petition," correct? 6 A Yes. 7 Q Okay. And as you sit here today, do you 8 know who it was that wrote the response? 9 A No. I would need to see what the 10 attachment is. 11 Q Okay. It says: "The attached draft 12 document has been prepared by J&J in response to 13 the Citizens Petition by the Cancer Prevention 14 Coalition." Correct? 15 A Yes. 16 Q And then attached to that -- 17 MR. LOCKE: Just for the record, this is 18 a document that says at the bottom "1 of 8," and 19 we only have one page. 20 BY MR. GOLOMB: 21 Q Which is the cover page to the 22 memorandum that went to the members of the Talc 23 Interested Party Task Force. 24 Is that consistent with your 25 understanding?</p>

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<p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: That's how I would read</p> <p>3 it.</p> <p>4 BY MR. GOLOMB:</p> <p>5 Q Have you seen this document before?</p> <p>6 A I don't know. I really need to see the</p> <p>7 attachment.</p> <p>8 Q Okay. I'm sorry, but I don't have</p> <p>9 copies of the attachment, but here's the draft.</p> <p>10 A (Peruses document.) Okay.</p> <p>11 MR. LOCKE: Since it's a J&J document,</p> <p>12 I'd like to send it down to their counsel just to</p> <p>13 see.</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q It's a -- just to be clear, it's a --</p> <p>16 you've now had an opportunity to see that draft,</p> <p>17 correct?</p> <p>18 A Yes.</p> <p>19 Q And have you seen that before?</p> <p>20 A I'm not sure.</p> <p>21 Q Okay. Did you see the -- the cover</p> <p>22 memorandum before?</p> <p>23 A If I had seen the cover, I would have</p> <p>24 seen the document, so I think I'm saying --</p> <p>25 Q Okay. And so --</p>	<p>1 record. Completing today's videotaped session.</p> <p>2 (Whereupon, the deposition of</p> <p>3 LINDA LORETZ, Ph.D. was adjourned</p> <p>4 at 5:03 p.m.)</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 A -- probably not, as I recall.</p> <p>2 Q So to be clear, in response to what</p> <p>3 Mr. Locke just said, the draft is a -- and the</p> <p>4 memorandum is a document which was produced by</p> <p>5 J&J, but it's a document on CTFA letterhead,</p> <p>6 correct?</p> <p>7 A Yes.</p> <p>8 Q Okay. But you haven't seen that before?</p> <p>9 MR. LOCKE: Well, wait.</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q That you can recall as you sit here.</p> <p>12 MR. LOCKE: This has a C -- this has a</p> <p>13 PCPC document and Bates number on it. So it came</p> <p>14 from PCPC's files. But it says on the cover page,</p> <p>15 "Prepared by J&J." That's what I was referring</p> <p>16 to.</p> <p>17 MR. GOLOMB: Okay. Fair enough.</p> <p>18 I think we're done for the day. That's</p> <p>19 the end of this subject, and we'll pick up</p> <p>20 tomorrow morning.</p> <p>21 MR. LOCKE: Okay.</p> <p>22 MR. GOLOMB: Let's go off the record,</p> <p>23 please.</p> <p>24 THE VIDEOGRAPHER: The time is</p> <p>25 5:03 p.m., October 1st, 2018. We're going off the</p>	<p>1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER</p> <p>2 The undersigned Certified Shorthand Reporter</p> <p>3 does hereby certify:</p> <p>4 That the foregoing proceeding was taken before</p> <p>5 me at the time and place therein set forth, at</p> <p>6 which time the witness was duly sworn; That the</p> <p>7 testimony of the witness and all objections made</p> <p>8 at the time of the examination were recorded</p> <p>9 stenographically by me and were thereafter</p> <p>10 transcribed, said transcript being a true and</p> <p>11 correct copy of my shorthand notes thereof; That</p> <p>12 the dismantling of the original transcript will</p> <p>13 void the reporter's certificate.</p> <p>14 In witness thereof, I have subscribed my name</p> <p>15 this date: October 2, 2018.</p> <p>16</p> <p>17 _____</p> <p>18 LESLIE A. TODD, CSR, RPR</p> <p>19 Certificate No. 5129</p> <p>20</p> <p>21 (The foregoing certification of</p> <p>22 this transcript does not apply to any</p> <p>23 reproduction of the same by any means,</p> <p>24 unless under the direct control and/or</p> <p>25 supervision of the certifying reporter.)</p>

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<p>1 INSTRUCTIONS TO WITNESS</p> <p>2 Please read your deposition over carefully and</p> <p>3 make any necessary corrections. You should state</p> <p>4 the reason in the appropriate space on the errata</p> <p>5 sheet for any corrections that are made.</p> <p>6 After doing so, please sign the errata sheet</p> <p>7 and date it.</p> <p>8 You are signing same subject to the changes</p> <p>9 you have noted on the errata sheet, which will be</p> <p>10 attached to your deposition. It is imperative</p> <p>11 that you return the original errata sheet to the</p> <p>12 deposing attorney within thirty (30) days of</p> <p>13 receipt of the deposition transcript by you. If</p> <p>14 you fail to do so, the deposition transcript may</p> <p>15 be deemed to be accurate and may be used in court.</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2 I, _____, do hereby</p> <p>3 certify that I have read the foregoing pages, and</p> <p>4 that the same is a correct transcription of the</p> <p>5 answers given by me to the questions therein</p> <p>6 propounded, except for the corrections or changes</p> <p>7 in form or substance, if any, noted in the</p> <p>8 attached Errata Sheet.</p> <p>9</p> <p>10 _____</p> <p>11 LINDA LORETZ, Ph.D. DATE</p> <p>12</p> <p>13</p> <p>14 Subscribed and sworn to</p> <p>15 before me this</p> <p>16 _____ day of _____, 20____.</p> <p>17 My commission expires: _____</p> <p>18 _____</p> <p>19 Notary Public</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p>Page 761</p> <p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p> <p>25</p>	

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Exhibit 135

Memorandum of Meeting

Date: May 8, 2009

Place: FDA, University Station Building, College Park, MD

Participants:

Visitors:

John Bailey, Ph.D., Personal Care Products Council
Linda Loretz, Ph.D., Personal Care Products Council
Kathleen Wille, Ph.D., Johnson & Johnson
David Mallon, Unilever
Craig Bernard, Ph.D., Rio Tinto Minerals (via telephone)
Jack Linard, Ph.D., Unilever (via telephone)
Shripal Sharma, Rio Tinto Minerals (via telephone)

FDA:

Linda Katz, M.D., M.P.H., Meeting Chair
Joshua Sharfstein, M.D.
Stephen Sundlof, D.V.M., Ph.D.
Robert Bronaugh, Ph.D.
Patricia Hansen, Ph.D.
Stanley Milstein, Ph.D.
Donald Havery
John Gasper, Minutes
Diego Rua, Ph.D.
Patrick McCarthy, Ph.D.

Subject: Talc

The meeting was held at the request of the Personal Care Products Council (PCPC). PCPC expressed their commitment to working with FDA on issues concerning cosmetic products containing talc. PCPC and the representatives of individual firms presented an analysis of the epidemiological association of cosmetic talc use with ovarian cancer, information regarding chemical and physical properties they believe differentiate cosmetic grade talc from other grades of talc, and different specifications used. FDA representatives indicated that they would like to see more detailed information on the chemical and physical properties of cosmetic grade talc, characterization and testing of cosmetic grade talc, commercial suppliers and users of cosmetic grade talc, and related information. Dr. Bailey of PCPC indicated that it might take some time to assemble all of the information, but that he would check with the members and get back to Dr. Katz on the timing. FDA representatives also indicated that if PCPC wished the Agency to consider the information in responding to citizen petitions, it should submit the information to the appropriate dockets. PCPC also indicated that they would consider



different mechanisms for strengthening the guidelines and procedures meant to assure the safety of talc used in cosmetics.

Action Items:

- Dr. Bailey to forward PCPC's expected responses to FDA questions (see attached) as soon as possible in 2 weeks. Additionally, PCPC will provide a list of talc suppliers along with their contact information.
- PCPC agreed to submit their prepared comments on: Citizen Petition to the Commissioner of the Food and Drug Administration Seeking a Cancer Warning on Talc Products to the docket.

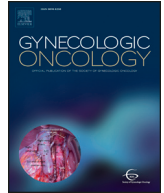
Exhibit 136



Contents lists available at ScienceDirect

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Talc and ovarian cancer

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HIGHLIGHTS

- Talc use has been linked to the risk of ovarian cancer in many case-control studies.
- Genital talc use is much less common now than it was in earlier cohorts of women in North America.
- It is not possible to say that any specific case of ovarian cancer was the result of talc use.

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Interest in a possible link between talcum powder and ovarian cancer risk dates back to the 1960s when the public was concerned about asbestos contamination in talc. Talc has been in the news intermittently since then, but the story of talc and ovarian cancer made the front page in February 2016, when the family of an ovarian cancer patient successfully sued Johnson and Johnson for 72 million dollars. This surprising jury decision raises a few questions. Is there a real and robust statistical association between talc use and ovarian cancer, and if so, is the association causal or due to confounding? What is the risk of cancer associated with talc use and how do we tell if a particular case of ovarian cancer was caused by talc? What should we tell our patients?

Most of the evidence comes from case-control studies. In 2013, the Ovarian Cancer Association Consortium pooled eight of these and analysed 8525 cases and 9859 controls [1]. They reported that genital powder use was associated with a modest but significant increased risk of epithelial ovarian cancer (OR = 1.24; 95% CI 1.15–1.33). The association between talc and ovarian cancer was significant in five of the eight individual studies. More recently, Cramer et al. studied 2041 cases and 2100 controls (some of whom were included in the OCAC study) [2]. They

estimated the risk of ovarian cancer associated with genital talc use to be 1.33 (95% CI 1.16 to 1.52). The case-control studies to date are consistent; given the small effect size it is not surprising that some are positive (i.e., show a significant increase in risk) and some are negative (i.e., show a non-significant increase in risk or no risk difference). Some say, based on this data, that there is little or no evidence that talc is associated with ovarian cancer. This is a conservative opinion, based on an uncompromising interpretation of statistics and a demand for proof. For the sake of argument, let us suppose that the true risk ratio for ever use of talc and the development of ovarian cancer is 1.2. This estimate is the one generated from the large pooling study [1] and is the level of risk that is under discussion in the media. It is possible that the true risk might be lower or higher than this single estimate. In this scenario, where talc increases the risk of ovarian cancer by 20% beyond the baseline of 1.3% lifetime, it would be challenging to convince the epidemiology community that there is a danger. Simply put, a risk ratio of this size falls outside the resolution of most epidemiologic studies; for example, if we set the *p*-value for significance at 0.05, then, in order to have a power of 0.80 to discriminate an increase in risk of 20%, and if 20% of the population is exposed to talc, we would require a case-control study of 2801 cases and 2801 controls. This is a very large sample for a case-control study, especially given that ovarian cancer is rare and only but the large study of Cramer et al the pooled analyses of OCAC were designed to detect and odds ratios this small [1,2]. If the

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magnitude of the association is to be estimated with precision it is important that consortia are developed and expanded in order to generate the appropriate sample size.

Prospective observational studies are less prone to bias than case-control studies, and for this reason they are given greater weight. In particular, they are not prone to recall bias (where the accuracy of the recollection of the exposure differs between cases and controls); selection bias (where the unexposed and exposed women are not equally likely to be ascertained for study) and survivorship bias (which would occur if the survival of women with ovarian cancer differs, depending on prior talc exposure. In the Nurses Health Study, 78,630 women were followed for a mean of 12.9 years [3]. There were 307 ovarian cancers diagnosed in the follow-up period. There was no overall association with ever-use of talc (HR = 1.09; 95% CI 0.86 to 1.37, but there was a modest and significant increased risk for serous ovarian cancer (HR = 1.40; 95% CI: 1.02–1.91). These figures could be dismissed as non-significant or as due to chance, but if the real risk were in fact 1.2, this is about what we would expect. In the Women's Health Initiative [4], 61,285 women were followed for an average of 12.4 years. 53% of the women reported perineal talc use (a very high proportion). The adjusted hazard ratio for serous ovarian cancer was 1.13, but this was not significant (95% CI 0.84 to 1.51). Neither prospective study confirmed the association of talc use and ovarian cancer raised by the case-control studies, but neither study was powered to detect a risk of 1.2 and therefore we cannot exclude the possibility. Only two women in a thousand will develop ovarian cancer in a ten-year follow up period. If we study 10,000 women over 10 years we can expect 20 cancers to occur. If the true odds ratio is 1.2, we will expect 20 cancers in an unexposed group of 10,000 women and 24 cancers in an exposed group of equal size and this difference will not be significant ($p = 0.65$). In order to achieve statistical significance in a prospective study, we need a much larger cohort, e.g., we will need to study upwards of 200,000 women for ten years.

Given this inherent limitation of cohort studies, it is not surprising that we have not been able to confirm the case-control studies with prospective studies, but this does not mean that the case-control studies were wrong. I don't think it is because the prospective studies are free from the biases that plague the case-control studies (e.g., recall bias) – I think the parsimonious explanation is that they lack statistical power. It is well that we also consider various possible biases as a source of imprecision in case-control studies. In the case of talc and ovarian cancer we should consider recall bias, survivorship bias and confounding bias. The idea behind recall bias is that a case is more likely to (correctly) recall the past use of talc than a control (who might forget) or that a case is more likely than a control to (incorrectly) report the use of talc that was never used. In studies where simple exposures that are coded as never/ever use recall bias unlikely to be an important source of bias. Survivorship bias would occur if we used prevalent cases and the use of talc was associated with better or worse survival, once ovarian cancer develops. There is no reason to assume that this is the case.

Confounding bias may be more subtle. When people say that 'association is not causality' they mean to say that that talc may not actually cause ovarian cancer but both talc and ovarian cancer may be linked to a third factor such as birth control pills – perhaps women who use talc are less likely to use birth control pills and therefore form a high risk group. Hardly likely – and the other risk factors for ovarian cancer are parity, breast feeding and tubal ligation. None of these are a priori likely to be confounders and in any case, most case-control studies will adjust for these. The most important potential confounder is year of birth (see below) and it is critical to control for this. It is unlikely that the association between talc and ovarian cancer is due to confounding and so it is fair to say that if there is a statistically robust relationship between talc use and ovarian cancer it is likely to be causal (albeit with intermediate factors such as inflammation). In any case, given the number of hazard ratios reported in the literature between 1.1 of 1.4 in both case-control and cohort studies, it is disingenuous to state that there is *no evidence* that talc is associated with ovarian cancer.

It has been suggested that talc passes through the cervix and endometrium and becomes lodged in the fallopian tube where it induces an inflammatory reaction [5]. This is hypothetical, but is supported by the observation of talc particles within the pelvic organs [6] and fits with the paradigm that most serous ovarian cancers originate in the fallopian tube and that intra-epithelial lesions in the fallopian epithelium are the earliest manifestations of an impending ovarian cancer [7]. If the model is correct, it is possible that the passage of talc is aided by retrograde menses and that talc use during menses poses a special risk. This might explain in part why the association between talc applied to sanitary napkins and ovarian cancer is among the most consistent. Against the model is the observation that, in the prospective studies, the relative risk of cancer associated with talc was not lower in women who had a tubal ligation [3,4] (and presumably had blocked access to talc).

If we accept that the actual hazard ratio for ever-use versus never-use is 1.2 how are we to interpret this number? If we consider a particular woman who uses talc regularly, her lifetime risk of ovarian cancer would increase from about 1.3% to 1.6%, an increase of 0.3% or three cases in a thousand. On a yearly scale, the risk rises from 20 per 100,000 women per year to 24 per 100,000 per year or four cancer cases for every 100,000 talc users. The latter might strike as more favorable, but, in fact describes the same risk. If we consider the population as a whole, the total number of ovarian cancer cases caused by talc depends on the frequency of talc use in the population. It is right to be concerned over the carcinogenicity of talc even if the risk ratio is low, because up to 50% of women are exposed [1]. If 40% of women use talc and the relative risk is 1.2, then 7% of ovarian cancer cases would be attributable to talc use or 1577 cases a year in the USA. This is not a trivial number and should not be dismissed. If 20% of women were talc users the number of cases per year would be 819. If only 5% of women use talc then the number of cases per year would be 211. Few perhaps, but if ovarian cancer is avoidable, it is best avoided. Is there a downside? Talc affords comfort and was used commonly in the past to control moisture and odor but women have many more choices nowadays. One could of course make a recommendation here not to use talc on sanitary napkins, but this will have little impact because few women continue to use it. In our database of 6000 women from North America that we follow at Women's College Hospital, the use of talc on sanitary napkins has declined precipitously from one generation to the next; talc use was recorded by 11% for women born from 1920 to 1940, but for only 1% of women born after 1975. Similarly, the use of talc applied directly to the genital area fell from 19% to 3% over the same period.

In the interests of public health, I believe we should caution women against using genital talcum powder. However, this policy of talc avoidance is unlikely to have much impact nowadays given this downward trend in usage. I don't think we should try to ascribe any particular case of ovarian cancer to prior talc use. The estimate of a risk ratio of 1.2 provides information about the potential contribution of talc to the burden of ovarian cancer in the population, but is not helpful in determining if a specific case is, or is not, the result of talc exposure. Are we able to make helpful recommendations for women who have used it in the past but who no longer use it? Probably not, we do not offer preventive surgery for women with a risk of ovarian cancer that is less than 2% and screening with CA125 or ultrasound is not recommended to women at average or slightly increased risk.

Conflict of interest

The author declares no conflict of interest.

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Exhibit 137



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Moving to a World Beyond " $p < 0.05$ "

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Moving to a World Beyond “ $p < 0.05$ ”

Some of you exploring this special issue of *The American Statistician* might be wondering if it's a scolding from pedantic statisticians lecturing you about what *not* to do with p -values, without offering any real ideas of what *to do* about the very hard problem of separating signal from noise in data and making decisions under uncertainty. Fear not. In this issue, thanks to 43 innovative and thought-provoking papers from forward-looking statisticians, help is on the way.

1. “Don’t” Is Not Enough

There's not much we can say here about the perils of p -values and significance testing that hasn't been said already for decades (Ziliak and McCloskey 2008; Hubbard 2016). If you're just arriving to the debate, here's a sampling of what not to do:

- Don't base your conclusions solely on whether an association or effect was found to be “statistically significant” (i.e., the p -value passed some arbitrary threshold such as $p < 0.05$).
- Don't believe that an association or effect exists just because it was statistically significant.
- Don't believe that an association or effect is absent just because it was not statistically significant.
- Don't believe that your p -value gives the probability that chance alone produced the observed association or effect or the probability that your test hypothesis is true.
- Don't conclude anything about scientific or practical importance based on statistical significance (or lack thereof).

Don't. Don't. Just...don't. Yes, we talk a lot about don'ts. The *ASA Statement on p -Values and Statistical Significance* (Wasserstein and Lazar 2016) was developed primarily because after decades, warnings about the don'ts had gone mostly unheeded. The statement was about what not to do, because there is widespread agreement about the don'ts.

Knowing what not to do with p -values is indeed necessary, but it does not suffice. It is as though statisticians were asking users of statistics to tear out the beams and struts holding up the edifice of modern scientific research without offering solid construction materials to replace them. Pointing out old, rotting timbers was a good start, but now we need more.

Recognizing this, in October 2017, the American Statistical Association (ASA) held the Symposium on Statistical Inference, a two-day gathering that laid the foundations for this

special issue of *The American Statistician*. Authors were explicitly instructed to develop papers for the variety of audiences interested in these topics. If you use statistics in research, business, or policymaking but are not a statistician, these articles were indeed written with YOU in mind. And if you are a statistician, there is still much here for you as well.

The papers in this issue propose many new ideas, ideas that in our determination as editors merited publication to enable broader consideration and debate. The ideas in this editorial are likewise open to debate. They are our own attempt to distill the wisdom of the many voices in this issue into an essence of good statistical practice as we currently see it: some do's for teaching, doing research, and informing decisions.

Yet the voices in the 43 papers in this issue do not sing as one. At times in this editorial and the papers you'll hear deep dissonance, the echoes of “statistics wars” still simmering today (Mayo 2018). At other times you'll hear melodies wrapping in a rich counterpoint that may herald an increasingly harmonious new era of statistics. To us, these are all the sounds of statistical inference in the 21st century, the sounds of a world learning to venture beyond “ $p < 0.05$.”

This is a world where researchers are free to treat “ $p = 0.051$ ” and “ $p = 0.049$ ” as not being categorically different, where authors no longer find themselves constrained to selectively publish their results based on a single magic number. In this world, where studies with “ $p < 0.05$ ” and studies with “ $p > 0.05$ ” are not automatically in conflict, researchers will see their results more easily replicated—and, even when not, they will better understand *why*. As we venture down this path, we will begin to see fewer false alarms, fewer overlooked discoveries, and the development of more customized statistical strategies. Researchers will be free to communicate all their findings in all their glorious uncertainty, knowing their work is to be judged by the quality and effective communication of their science, and not by their p -values. As “statistical significance” is used less, statistical thinking will be used more.

The *ASA Statement on P -Values and Statistical Significance* started moving us toward this world. As of the date of publication of this special issue, the statement has been viewed over 294,000 times and cited over 1700 times—an average of about 11 citations per week since its release. Now we must go further. That's what this special issue of *The American Statistician* sets out to do.

To get to the do's, though, we must begin with one more don't.

2. Don't Say "Statistically Significant"

The ASA *Statement on P-Values and Statistical Significance* stopped just short of recommending that declarations of "statistical significance" be abandoned. We take that step here. We conclude, based on our review of the articles in this special issue and the broader literature, that it is time to stop using the term "statistically significant" entirely. Nor should variants such as "significantly different," " $p < 0.05$," and "nonsignificant" survive, whether expressed in words, by asterisks in a table, or in some other way.

Regardless of whether it was ever useful, a declaration of "statistical significance" has today become meaningless. Made broadly known by Fisher's use of the phrase (1925), Edgeworth's (1885) original intention for statistical significance was simply as a tool to indicate when a result warrants further scrutiny. But that idea has been irretrievably lost. Statistical significance was never meant to imply scientific importance, and the confusion of the two was decried soon after its widespread use (Boring 1919). Yet a full century later the confusion persists.

And so the tool has become the tyrant. The problem is not simply use of the word "significant," although the statistical and ordinary language meanings of the word are indeed now hopelessly confused (Ghose 2013); the term should be avoided for that reason alone. The problem is a larger one, however: using bright-line rules for justifying scientific claims or conclusions can lead to erroneous beliefs and poor decision making (ASA statement, Principle 3). A label of statistical significance adds nothing to what is already conveyed by the value of p ; in fact, this dichotomization of p -values makes matters worse.

For example, no p -value can reveal the plausibility, presence, truth, or importance of an association or effect. Therefore, a label of statistical significance does not mean or imply that an association or effect is highly probable, real, true, or important. Nor does a label of statistical nonsignificance lead to the association or effect being improbable, absent, false, or unimportant. Yet the dichotomization into "significant" and "not significant" is taken as an imprimatur of authority on these characteristics. In a world without bright lines, on the other hand, it becomes untenable to assert dramatic differences in interpretation from inconsequential differences in estimates. As Gelman and Stern (2006) famously observed, the difference between "significant" and "not significant" is not itself statistically significant.

Furthermore, this false split into "worthy" and "unworthy" results leads to the selective reporting and publishing of results based on their statistical significance—the so-called "file drawer problem" (Rosenthal 1979). And the dichotomized reporting problem extends beyond just publication, notes Amrhein, Trafimow, and Greenland (2019): when authors use p -value thresholds to select which findings to discuss in their papers, "their conclusions and what is reported in subsequent news and reviews will be biased...Such selective attention based on study outcomes will therefore not only distort the literature but will slant published descriptions of study results—biasing the summary descriptions reported to practicing professionals and the general public." For the integrity of scientific publishing and research dissemination, therefore, whether a p -value passes any arbitrary threshold should not be considered at all when deciding which results to present or highlight.

To be clear, the problem is not that of having only two labels. Results should not be trichotomized, or indeed categorized into any number of groups, based on arbitrary p -value thresholds. Similarly, we need to stop using confidence intervals as another means of dichotomizing (based, on whether a null value falls within the interval). And, to preclude a reappearance of this problem elsewhere, we must not begin arbitrarily categorizing other statistical measures (such as Bayes factors).

Despite the limitations of p -values (as noted in Principles 5 and 6 of the ASA statement), however, we are not recommending that the calculation and use of continuous p -values be discontinued. Where p -values are used, they should be reported as continuous quantities (e.g., $p = 0.08$). They should also be described in language stating what the value means in the scientific context. We believe that a reasonable prerequisite for reporting any p -value is the ability to interpret it appropriately. We say more about this in Section 3.3.

To move forward to a world beyond " $p < 0.05$," we must recognize afresh that statistical inference is not—and never has been—equivalent to scientific inference (Hubbard, Haig, and Parsa 2019; Ziliak 2019). However, looking to statistical significance for a marker of scientific observations' credibility has created a guise of equivalency. Moving beyond "statistical significance" opens researchers to the real significance of statistics, which is "the science of learning from data, and of measuring, controlling, and communicating uncertainty" (Davidian and Louis 2012).

In sum, "statistically significant"—don't say it and don't use it.

3. There Are Many Do's

With the don'ts out of the way, we can finally discuss ideas for specific, positive, constructive actions. We have a massive list of them in the seventh section of this editorial! In that section, the authors of all the articles in this special issue each provide their own short set of do's. Those lists, and the rest of this editorial, will help you navigate the substantial collection of articles that follows.

Because of the size of this collection, we take the liberty here of distilling our readings of the articles into a summary of what can be done to move beyond " $p < 0.05$." You will find the rich details in the articles themselves.

What you will NOT find in this issue is one solution that majestically replaces the outsized role that statistical significance has come to play. The statistical community has not yet converged on a simple paradigm for the use of statistical inference in scientific research—and in fact it may never do so. A one-size-fits-all approach to statistical inference is an inappropriate expectation, even after the dust settles from our current remodeling of statistical practice (Tong 2019). Yet solid principles for the use of statistics do exist, and they are well explained in this special issue.

We summarize our recommendations in two sentences totaling seven words: "Accept uncertainty. Be thoughtful, open, and modest." Remember "ATOM."

3.1. Accept Uncertainty

Uncertainty exists everywhere in research. And, just like with the frigid weather in a Wisconsin winter, there are those who will flee from it, trying to hide in warmer havens elsewhere. Others, however, accept and even delight in the omnipresent cold; these are the ones who buy the right gear and bravely take full advantage of all the wonders of a challenging climate. Significance tests and dichotomized p -values have turned many researchers into scientific snowbirds, trying to avoid dealing with uncertainty by escaping to a “happy place” where results are either statistically significant or not. In the real world, data provide a noisy signal. Variation, one of the causes of uncertainty, is everywhere. Exact replication is difficult to achieve. So it is time to get the right (statistical) gear and “move toward a greater acceptance of uncertainty and embracing of variation” (Gelman 2016).

Statistical methods do not rid data of their uncertainty. “Statistics,” Gelman (2016) says, “is often sold as a sort of alchemy that transmutes randomness into certainty, an ‘uncertainty laundering’ that begins with data and concludes with success as measured by statistical significance.” To accept uncertainty requires that we “treat statistical results as being much more incomplete and uncertain than is currently the norm” (Amrhein, Trafimow, and Greenland 2019). We must “countenance uncertainty in all statistical conclusions, seeking ways to quantify, visualize, and interpret the potential for error” (Calin-Jageman and Cumming 2019).

“Accept uncertainty and embrace variation in effects,” advise McShane et al. in Section 7 of this editorial. “[W]e can learn much (indeed, more) about the world by forsaking the false promise of certainty offered by dichotomous declarations of truth or falsity—binary statements about there being ‘an effect’ or ‘no effect’—based on some p -value or other statistical threshold being attained.”

We can make acceptance of uncertainty more natural to our thinking by accompanying every point estimate in our research with a measure of its uncertainty such as a standard error or interval estimate. Reporting and interpreting point and interval estimates should be routine. However, simplistic use of confidence intervals as a measurement of uncertainty leads to the same bad outcomes as use of statistical significance (especially, a focus on whether such intervals include or exclude the “null hypothesis value”). Instead, Greenland (2019) and Amrhein, Trafimow, and Greenland (2019) encourage thinking of confidence intervals as “compatibility intervals,” which use p -values to show the effect sizes that are most compatible with the data under the given model.

How will **accepting uncertainty** change anything? To begin, it will prompt us to seek better measures, more sensitive designs, and larger samples, all of which increase the rigor of research. It also helps us **be modest** (the fourth of our four principles, on which we will expand in Section 3.4) and encourages “meta-analytic thinking” (Cumming 2014). Accepting uncertainty as inevitable is a natural antidote to the seductive certainty falsely promised by statistical significance. With this new outlook, we will naturally seek out replications and the integration of evidence through meta-analyses, which usually requires point and interval estimates from contributing studies. This will in

turn give us more precise overall estimates for our effects and associations. And this is what will lead to the best research-based guidance for practical decisions.

Accepting uncertainty leads us to **be thoughtful**, the second of our four principles.

3.2. Be Thoughtful

What do we mean by this exhortation to “be thoughtful”? Researchers already clearly put much thought into their work. We are not accusing anyone of laziness. Rather, we are envisioning a sort of “statistical thoughtfulness.” In this perspective, statistically **thoughtful researchers** begin above all else with clearly expressed objectives. They recognize when they are doing exploratory studies and when they are doing more rigidly pre-planned studies. They invest in producing solid data. They consider not one but a multitude of data analysis techniques. And they think about so much more.

3.2.1. Thoughtfulness in the Big Picture

“[M]ost scientific research is exploratory in nature,” Tong (2019) contends. “[T]he design, conduct, and analysis of a study are necessarily flexible, and must be open to the discovery of unexpected patterns that prompt new questions and hypotheses. In this context, statistical modeling can be exceedingly useful for elucidating patterns in the data, and researcher degrees of freedom can be helpful and even essential, though they still carry the risk of overfitting. The price of allowing this flexibility is that the validity of any resulting statistical inferences is undermined.”

Calin-Jageman and Cumming (2019) caution that “in practice the dividing line between planned and exploratory research can be difficult to maintain. Indeed, exploratory findings have a slippery way of ‘transforming’ into planned findings as the research process progresses.” At the bottom of that slippery slope one often finds results that don’t reproduce.

Anderson (2019) proposes three questions **thoughtful researchers** asked thoughtful researchers evaluating research results: What are the practical implications of the estimate? How precise is the estimate? And is the model correctly specified? The latter question leads naturally to three more: Are the modeling assumptions understood? Are these assumptions valid? And do the key results hold up when other modeling choices are made? Anderson further notes, “Modeling assumptions (including all the choices from model specification to sample selection and the handling of data issues) should be sufficiently documented so independent parties can critique, and replicate, the work.”

Drawing on archival research done at the Guinness Archives in Dublin, Ziliak (2019) emerges with ten “ G -values” he believes we all wish to maximize in research. That is, we want large G -values, not small p -values. The ten principles of Ziliak’s “Guinnessometrics” are derived primarily from his examination of experiments conducted by statistician William Sealy Gosset while working as Head Brewer for Guinness. Gosset took an economic approach to the logic of uncertainty, preferring balanced designs over random ones and estimation of gambles over bright-line “testing.” Take, for example, Ziliak’s G -value 10: “Consider purpose of the inquiry, and compare with best

practice,” in the spirit of what farmers and brewers must do. The purpose is generally NOT to falsify a null hypothesis, says Ziliak. Ask what is at stake, he advises, and determine what magnitudes of change are humanly or scientifically meaningful in context.

Pogrow (2019) offers an approach based on practical benefit rather than statistical or practical significance. This approach is especially useful, he says, for assessing whether interventions in complex organizations (such as hospitals and schools) are effective, and also for increasing the likelihood that the observed benefits will replicate in subsequent research and in clinical practice. In this approach, “practical benefit” recognizes that reliance on small effect sizes can be as problematic as relying on p -values.

Thoughtful research prioritizes sound data production by putting energy into the careful planning, design, and execution of the study (Tong 2019).

Locascio (2019) urges researchers to be prepared for a new publishing model that evaluates their research based on the importance of the questions being asked and the methods used to answer them, rather than the outcomes obtained.

3.2.2. Thoughtfulness Through Context and Prior Knowledge

Thoughtful research considers the scientific context and prior evidence. In this regard, a declaration of statistical significance is the antithesis of thoughtfulness: it says nothing about practical importance, and it ignores what previous studies have contributed to our knowledge.

Thoughtful research looks ahead to prospective outcomes in the context of theory and previous research. Researchers would do well to ask, *What do we already know, and how certain are we in what we know?* And building on that and on the field’s theory, *what magnitudes of differences, odds ratios, or other effect sizes are practically important?* These questions would naturally lead a researcher, for example, to use existing evidence from a literature review to identify specifically the findings that would be practically important for the key outcomes under study.

Thoughtful research includes careful consideration of the definition of a meaningful effect size. As a researcher you should communicate this up front, before data are collected and analyzed. Afterwards is just too late; it is dangerously easy to justify observed results after the fact and to overinterpret trivial effect sizes as being meaningful. Many authors in this special issue argue that consideration of the effect size and its “scientific meaningfulness” is essential for reliable inference (e.g., Blume et al. 2019; Betensky 2019). This concern is also addressed in the literature on equivalence testing (Wellek 2017).

Thoughtful research considers “related prior evidence, plausibility of mechanism, study design and data quality, real world costs and benefits, novelty of finding, and other factors that vary by research domain...without giving priority to p -values or other purely statistical measures” (McShane et al. 2019).

Thoughtful researchers “use a toolbox of statistical techniques, employ good judgment, and keep an eye on developments in statistical and data science,” conclude Heck and Krueger (2019), who demonstrate how the p -value can be useful to researchers as a heuristic.

3.2.3. Thoughtful Alternatives and Complements to P -Values

Thoughtful research considers multiple approaches for solving problems. This special issue includes some ideas for supplementing or replacing p -values. Here is a short summary of some of them, with a few technical details:

Amrhein, Trafimow, and Greenland (2019) and Greenland (2019) advise that null p -values should be supplemented with a p -value from a test of a pre-specified alternative (such as a minimal important effect size). To reduce confusion with posterior probabilities and better portray evidential value, they further advise that p -values be transformed into s -values (Shannon information, surprisal, or binary logworth) $s = -\log_2(p)$. This measure of evidence affirms other arguments that the evidence against a hypothesis contained in the p -value is not nearly as strong as is believed by many researchers. The change of scale also moves users away from probability misinterpretations of the p -value.

Blume et al. (2019) offer a “second generation p -value (SGPV),” the characteristics of which mimic or improve upon those of p -values but take practical significance into account. The null hypothesis from which an SGPV is computed is a composite hypothesis representing a range of differences that would be practically or scientifically inconsequential, as in equivalence testing (Wellek 2017). This range is determined in advance by the experimenters. When the SGPV is 1, the data only support null hypotheses; when the SGPV is 0, the data are incompatible with any of the null hypotheses. SGPVs between 0 and 1 are inconclusive at varying levels (maximally inconclusive at or near SGPV = 0.5.) Blume et al. illustrate how the SGPV provides a straightforward and useful descriptive summary of the data. They argue that it eliminates the problem of how classical statistical significance does not imply scientific relevance, it lowers false discovery rates, and its conclusions are more likely to reproduce in subsequent studies.

The “analysis of credibility”(AnCred) is promoted by Matthews (2019). This approach takes account of both the width of the confidence interval and the location of its bounds when assessing weight of evidence. AnCred assesses the credibility of inferences based on the confidence interval by determining the level of prior evidence needed for a new finding to provide credible evidence for a nonzero effect. If this required level of prior evidence is supported by current knowledge and insight, Matthews calls the new result “credible evidence for a non-zero effect,” irrespective of its statistical significance/nonsignificance.

Colquhoun (2019) proposes continuing the use of continuous p -values, but only in conjunction with the “false positive risk (FPR).” The FPR answers the question, “If you observe a ‘significant’ p -value after doing a single unbiased experiment, what is the probability that your result is a false positive?” It tells you what most people mistakenly still think the p -value does, Colquhoun says. The problem, however, is that to calculate the FPR you need to specify the prior probability that an effect is real, and it’s rare to know this. Colquhoun suggests that the FPR could be calculated with a prior probability of 0.5, the largest value reasonable to assume in the absence of hard prior data. The FPR found this way is in a sense the minimum false positive risk (mFPR); less plausible hypotheses (prior probabilities below 0.5) would give even bigger FPRs, Colquhoun says, but the

mFPR would be a big improvement on reporting a p -value alone. He points out that p -values near 0.05 are, under a variety of assumptions, associated with minimum false positive risks of 20–30%, which should stop a researcher from making too big a claim about the “statistical significance” of such a result.

Benjamin and Berger (2019) propose a different supplement to the null p -value. The Bayes factor bound (BFB)—which under typically plausible assumptions is the value $1/(-ep \ln p)$ —represents the upper bound of the ratio of data-based odds of the alternative hypothesis to the null hypothesis. Benjamin and Berger advise that the BFB should be reported along with the continuous p -value. This is an incomplete step toward revising practice, they argue, but one that at least confronts the researcher with the maximum possible odds that the alternative hypothesis is true—which is what researchers often think they are getting with a p -value. The BFB, like the FPR, often clarifies that the evidence against the null hypothesis contained in the p -value is not nearly as strong as is believed by many researchers.

Goodman, Spruill, and Komaroff (2019) propose a two-stage approach to inference, requiring both a small p -value below a pre-specified level and a pre-specified sufficiently large effect size before declaring a result “significant.” They argue that this method has improved performance relative to use of dichotomized p -values alone.

Gannon, Pereira, and Polpo (2019) have developed a testing procedure combining frequentist and Bayesian tools to provide a significance level that is a function of sample size.

Manski (2019) and Manski and Tetenov (2019) urge a return to the use of statistical decision theory, which they say has largely been forgotten. Statistical decision theory is not based on p -value thresholds and readily distinguishes between statistical and clinical significance.

Billheimer (2019) suggests abandoning inference about parameters, which are frequently hypothetical quantities used to idealize a problem. Instead, he proposes focusing on the prediction of future observables, and their associated uncertainty, as a means to improving science and decision-making.

3.2.4. *Thoughtful Communication of Confidence*

Be thoughtful and clear about the level of confidence or credibility that is present in statistical results.

Amrhein, Trafimow, and Greenland (2019) and Greenland (2019) argue that the use of words like “significance” in conjunction with p -values and “confidence” with interval estimates misleads users into overconfident claims. They propose that researchers think of p -values as measuring the compatibility between hypotheses and data, and interpret interval estimates as “compatibility intervals.”

In what may be a controversial proposal, Goodman (2018) suggests requiring “that any researcher making a claim in a study accompany it with their estimate of the chance that the claim is true.” Goodman calls this the confidence index. For example, along with stating “This drug is associated with elevated risk of a heart attack, relative risk (RR) = 2.4, p = 0.03,” Goodman says investigators might add a statement such as “There is an 80% chance that this drug raises the risk, and a 60% chance that the risk is at least doubled.” Goodman acknowledges, “Although

simple on paper, requiring a confidence index would entail a profound overhaul of scientific and statistical practice.”

In a similar vein, Hubbard and Carriquiry (2019) urge that researchers prominently display the probability the hypothesis is true or a probability distribution of an effect size, or provide sufficient information for future researchers and policy makers to compute it. The authors further describe why such a probability is necessary for decision making, how it could be estimated by using historical rates of reproduction of findings, and how this same process can be part of continuous “quality control” for science.

Being thoughtful in our approach to research will lead us to **be open** in our design, conduct, and presentation of it as well.

3.3. *Be Open*

We envision **openness** as embracing certain positive practices in the development and presentation of research work.

3.3.1. *Openness to Transparency and to the Role of Expert Judgment*

First, we repeat oft-repeated advice: **Be open** to “open science” practices. Calin-Jageman and Cumming (2019), Locascio (2019), and others in this special issue urge adherence to practices such as public pre-registration of methods, transparency and completeness in reporting, shared data and code, and even pre-registered (“results-blind”) review. Completeness in reporting, for example, requires not only describing all analyses performed but also presenting all findings obtained, without regard to statistical significance or any such criterion.

Openness also includes understanding and accepting the role of expert judgment, which enters the practice of statistical inference and decision-making in numerous ways (O’Hagan 2019). “Indeed, there is essentially no aspect of scientific investigation in which judgment is not required,” O’Hagan observes. “Judgment is necessarily subjective, but should be made as carefully, as objectively, and as scientifically as possible.”

Subjectivity is involved in any statistical analysis, Bayesian or frequentist. Gelman and Hennig (2017) observe, “Personal decision making cannot be avoided in statistical data analysis and, for want of approaches to justify such decisions, the pursuit of objectivity degenerates easily to a pursuit to merely *appear* objective.” One might say that subjectivity is not a problem; it is part of the solution.

Acknowledging this, Brownstein et al. (2019) point out that expert judgment and knowledge are required in all stages of the scientific method. They examine the roles of expert judgment throughout the scientific process, especially regarding the integration of statistical and content expertise. “All researchers, irrespective of their philosophy or practice, use expert judgment in developing models and interpreting results,” say Brownstein et al. “We must accept that there is subjectivity in every stage of scientific inquiry, but objectivity is nevertheless the fundamental goal. Therefore, we should base judgments on evidence and careful reasoning, and seek wherever possible to eliminate potential sources of bias.”

How does one rigorously elicit expert knowledge and judgment in an effective, unbiased, and transparent way? O'Hagan (2019) addresses this, discussing protocols to elicit expert knowledge in an unbiased and as scientifically sound was as possible. It is also important for such elicited knowledge to be examined critically, comparing it to actual study results being an important diagnostic step.

3.3.2. Openness in Communication

Be open in your reporting. Report p -values as continuous, descriptive statistics, as we explain in Section 2. We realize that this leaves researchers without their familiar bright line anchors. Yet if we were to propose a universal template for presenting and interpreting continuous p -values we would violate our own principles! Rather, we believe that the thoughtful use and interpretation of p -values will never adhere to a rigid rulebook, and will instead inevitably vary from study to study. Despite these caveats, we can offer recommendations for sound practices, as described below.

In all instances, regardless of the value taken by p or any other statistic, consider what McShane et al. (2019) call the “currently subordinate factors”—the factors that should no longer be subordinate to “ $p < 0.05$.” These include relevant prior evidence, plausibility of mechanism, study design and data quality, and the real-world costs and benefits that determine what effects are scientifically important. The scientific context of your study matters, they say, and this should guide your interpretation.

When using p -values, remember not only Principle 5 of the ASA statement: “A p -value...does not measure the size of an effect or the importance of a result” but also Principle 6: “By itself, a p -value does not provide a good measure of evidence regarding a model or hypothesis.” Despite these limitations, if you present p -values, do so for more than one hypothesized value of your variable of interest (Fraser 2019; Greenland 2019), such as 0 and at least one plausible, relevant alternative, such as the minimum practically important effect size (which should be determined before analyzing the data).

Betensky (2019) also reminds us to interpret the p -value in the context of sample size and meaningful effect size.

Instead of p , you might consider presenting the s -value (Greenland 2019), which is described in Section 3.2. As noted in Section 3.1, you might present a confidence interval. Sound practices in the interpretation of confidence intervals include (1) discussing both the upper and lower limits and whether they have different practical implications, (2) paying no particular attention to whether the interval includes the null value, and (3) remembering that an interval is itself an estimate subject to error and generally provides only a rough indication of uncertainty given that all of the assumptions used to create it are correct and, thus, for example, does not “rule out” values outside the interval. Amrhein, Trafimow, and Greenland (2019) suggest that interval estimates be interpreted as “compatibility” intervals rather than as “confidence” intervals, showing the values that are most compatible with the data, under the model used to compute the interval. They argue that such an interpretation and the practices outlined here can help guard against overconfidence.

It is worth noting that Tong (2019) disagrees with using p -values as descriptive statistics. “Divorced from the probability

claims attached to such quantities (confidence levels, nominal Type I errors, and so on), there is no longer any reason to privilege such quantities over descriptive statistics that more directly characterize the data at hand.” He further states, “Methods with alleged generality, such as the p -value or Bayes factor, should be avoided in favor of discipline- and problem-specific solutions that can be designed to be fit for purpose.”

Failing to **be open** in reporting leads to publication bias. Ioannidis (2019) notes the high level of selection bias prevalent in biomedical journals. He defines “selection” as “the collection of choices that lead from the planning of a study to the reporting of p -values.” As an illustration of one form of selection bias, Ioannidis compared “the set of p -values reported in the full text of an article with the set of p -values reported in the abstract.” The main finding, he says, “was that p -values chosen for the abstract tended to show greater significance than those reported in the text, and that the gradient was more pronounced in some types of journals and types of designs.” Ioannidis notes, however, that selection bias “can be present regardless of the approach to inference used.” He argues that in the long run, “the only direct protection must come from standards for reproducible research.”

To **be open**, remember that one study is rarely enough. The words “a groundbreaking new study” might be loved by news writers but must be resisted by researchers. Breaking ground is only the first step in building a house. It will be suitable for habitation only after much more hard work.

Be open by providing sufficient information so that other researchers can execute meaningful alternative analyses. van Dongen et al. (2019) provide an illustrative example of such alternative analyses by different groups attacking the same problem.

Being open goes hand in hand with **being modest**.

3.4. Be Modest

Researchers of any ilk may rarely advertise their personal modesty. Yet the most successful ones cultivate a practice of **being modest** throughout their research, by understanding and clearly expressing the limitations of their work.

Being modest requires a reality check (Amrhein, Trafimow, and Greenland 2019). “A core problem,” they observe, “is that both scientists and the public confound statistics with reality. But statistical inference is a thought experiment, describing the predictive performance of models about reality. Of necessity, these models are extremely simplified relative to the complexities of actual study conduct and of the reality being studied. Statistical results must eventually mislead us when they are used and communicated as if they present this complex reality, rather than a model for it. This is not a problem of our statistical methods. It is a problem of interpretation and communication of results.”

Be modest in recognizing there is not a “true statistical model” underlying every problem, which is why it is wise to **thoughtfully** consider many possible models (Lavine 2019). Rougier (2019) calls on researchers to “recognize that behind every choice of null distribution and test statistic, there lurks

a plausible family of alternative hypotheses, which can provide more insight into the null distribution.”

p -values, confidence intervals, and other statistical measures are all uncertain. Treating them otherwise is immodest overconfidence.

Remember that statistical tools have their limitations. Rose and McGuire (2019) show how use of stepwise regression in health care settings can lead to policies that are unfair.

Remember also that the amount of evidence for or against a hypothesis provided by p -values near the ubiquitous $p < 0.05$ threshold (Johnson 2019) is usually much less than you think (Benjamin and Berger 2019; Colquhoun 2019; Greenland 2019).

Be modest about the role of statistical inference in scientific inference. “Scientific inference is a far broader concept than statistical inference,” says Hubbard, Haig, and Parsa (2019). “A major focus of scientific inference can be viewed as the pursuit of *significant sameness*, meaning replicable and empirically generalizable results among phenomena. Regrettably, the obsession with users of statistical inference to report *significant differences* in data sets actively thwarts cumulative knowledge development.”

The nexus of **openness** and **modesty** is to report everything while at the same time not concluding anything from a single study with unwarranted certainty. Because of the strong desire to inform and be informed, there is a relentless demand to state results with certainty. Again, **accept uncertainty** and embrace variation in associations and effects, because they are always there, like it or not. Understand that expressions of uncertainty are themselves uncertain. Accept that one study is rarely definitive, so encourage, sponsor, conduct, and publish replication studies. Then, use meta-analysis, evidence reviews, and Bayesian methods to synthesize evidence across studies.

Resist the urge to overreach in the generalizability of claims. Watch out for pressure to embellish the abstract or the press release. If the study’s limitations are expressed in the paper but not in the abstract, they may never be read.

Be modest by encouraging others to reproduce your work. Of course, for it to be reproduced readily, you will necessarily have been **thoughtful** in conducting the research and **open** in presenting it.

Hubbard and Carriquiry (see their “do list” in Section 7) suggest encouraging reproduction of research by giving “a byline status for researchers who reproduce studies.” They would like to see digital versions of papers dynamically updated to display “Reproduced by....” below original research authors’ names or “not yet reproduced” until it is reproduced.

Indeed, when it comes to reproducibility, Amrhein, Trafimow, and Greenland (2019) demand that we **be modest** in our expectations. “An important role for statistics in research is the summary and accumulation of information,” they say. “If replications do not find the same results, this is not necessarily a crisis, but is part of a natural process by which science evolves. The goal of scientific methodology should be to direct this evolution toward ever more accurate descriptions of the world and how it works, not toward ever more publication of inferences, conclusions, or decisions.”

Referring to replication studies in psychology, McShane et al. (2019) recommend that future large-scale replication projects “should follow the ‘one phenomenon, many studies’ approach

of the Many Labs project and Registered Replication Reports rather than the ‘many phenomena, one study’ approach of the Open Science Collaboration project. In doing so, they should systematically vary method factors across the laboratories involved in the project.” This approach helps achieve the goals of Amrhein, Trafimow, and Greenland (2019) by increasing understanding of why and when results replicate or fail to do so, yielding more accurate descriptions of the world and how it works. It also speaks to significant sameness versus significant difference a la Hubbard, Haig, and Parsa (2019).

Kennedy-Shaffer’s (2019) historical perspective on statistical significance reminds us to **be modest**, by prompting us to recall how the current state of affairs in p -values has come to be.

Finally, **be modest** by recognizing that different readers may have very different stakes on the results of your analysis, which means you should try to take the role of a neutral judge rather than an advocate for any hypothesis. This can be done, for example, by pairing every null p -value with a p -value testing an equally reasonable alternative, and by discussing the endpoints of every interval estimate (not only whether it contains the null).

Accept that both scientific inference and statistical inference are hard, and understand that no knowledge will be efficiently advanced using simplistic, mechanical rules and procedures. Accept also that pure objectivity is an unattainable goal—no matter how laudable—and that both subjectivity and expert judgment are intrinsic to the conduct of science and statistics. Accept that there will always be uncertainty, and be **thoughtful**, **open**, and **modest**. ATOM.

And to push this acronym further, we argue in the next section that institutional change is needed, so we put forward that change is needed at the ATOMIC level. Let’s go.

4. Editorial, Educational and Other Institutional Practices Will Have to Change

Institutional reform is necessary for moving beyond statistical significance in any context—whether journals, education, academic incentive systems, or others. Several papers in this special issue focus on reform.

Goodman (2019) notes considerable social change is needed in academic institutions, in journals, and among funding and regulatory agencies. He suggests (see Section 7) partnering “with science reform movements and reformers within disciplines, journals, funding agencies and regulators to promote and reward ‘reproducible’ science and diminish the impact of statistical significance on publication, funding and promotion.” Similarly, Colquhoun (2019) says, “In the end, the only way to solve the problem of reproducibility is to do more replication and to reduce the incentives that are imposed on scientists to produce unreliable work. The publish-or-perish culture has damaged science, as has the judgment of their work by silly metrics.”

Trafimow (2019), who added energy to the discussion of p -values a few years ago by banning them from the journal he edits (Fricker et al. 2019), suggests five “nonobvious changes” to editorial practice. These suggestions, which demand reevaluating traditional practices in editorial policy, will not be trivial to implement but would result in massive change in some journals.

Locascio (2017, 2019) suggests that evaluation of manuscripts for publication should be “results-blind.” That is, manuscripts should be assessed for suitability for publication based on the substantive importance of the research without regard to their reported results. Kmetz (2019) supports this approach as well and says that it would be a huge benefit for reviewers, “freeing [them] from their often thankless present jobs and instead allowing them to review research designs for their potential to provide useful knowledge.” (See also “registered reports” from the Center for Open Science (https://cos.io/rr/?_ga=2.184185454.979594832.1547755516-1193527346.1457026171) and “registered replication reports” from the Association for Psychological Science (<https://www.psychologicalscience.org/publications/replication>) in relation to this concept.)

Amrhein, Trafimow, and Greenland (2019) ask if results-blind publishing means that anything goes, and then answer affirmatively: “Everything should be published in some form if whatever we measured made sense *before we obtained the data* because it was connected in a potentially useful way to some research question.” Journal editors, they say, “should be proud about [their] exhaustive methods sections” and base their decisions about the suitability of a study for publication “on the quality of its materials and methods rather than on results and conclusions; the quality of the presentation of the latter is only judged after it is determined that the study is valuable based on its materials and methods.”

A “variation on this theme is *pre-registered replication*, where a *replication* study, rather than the original study, is subject to strict pre-registration (e.g., Gelman 2015),” says Tong (2019). “A broader vision of this idea (Mogil and Macleod 2017) is to carry out a whole series of exploratory experiments *without* any formal statistical inference, and summarize the results by descriptive statistics (including graphics) or even just disclosure of the raw data. When results from this series of experiments converge to a single working hypothesis, it can *then* be subjected to a pre-registered, randomized and blinded, appropriately powered confirmatory experiment, carried out by another laboratory, in which valid statistical inference may be made.”

Hurlbert, Levine, and Utts (2019) urge abandoning the use of “statistically significant” in all its forms and encourage journals to provide instructions to authors along these lines: “There is now wide agreement among many statisticians who have studied the issue that for reporting of statistical tests yielding *p*-values it is illogical and inappropriate to dichotomize the *p*-scale and describe results as ‘significant’ and ‘nonsignificant.’ Authors are strongly discouraged from continuing this never justified practice that originated from confusions in the early history of modern statistics.”

Hurlbert, Levine, and Utts (2019) also urge that the ASA *Statement on P-Values and Statistical Significance* “be sent to the editor-in-chief of every journal in the natural, behavioral and social sciences for forwarding to their respective editorial boards and stables of manuscript reviewers. That would be a good way to quickly improve statistical understanding and practice.” Kmetz (2019) suggests referring to the ASA statement whenever submitting a paper or revision to any editor, peer reviewer, or prospective reader. Hurlbert et al. encourage a “community grassroots effort” to encourage change in journal procedures.

Campbell and Gustafson (2019) propose a statistical model for evaluating publication policies in terms of weighing novelty of studies (and the likelihood of those studies subsequently being found false) against pre-specified study power. They observe that “no publication policy will be perfect. Science is inherently challenging and we must always be willing to accept that a certain proportion of research is potentially false.”

Statistics education will require major changes at all levels to move to a post “ $p < 0.05$ ” world. Two papers in this special issue make a specific start in that direction (Maurer et al. 2019; Steel, Liermann, and Guttorp 2019), but we hope that volumes will be written on this topic in other venues. We are excited that, with support from the ASA, the US Conference on Teaching Statistics (USCOTS) will focus its 2019 meeting on teaching inference.

The change that needs to happen demands change to editorial practice, to the teaching of statistics at every level where inference is taught, and to much more. However...

5. It Is Going to Take Work, and It Is Going to Take Time

If it were easy, it would have already been done, because as we have noted, this is nowhere near the first time the alarm has been sounded.

Why is eliminating the use of *p*-values as a truth arbiter so hard? “The basic explanation is neither philosophical nor scientific, but sociologic; everyone uses them,” says Goodman (2019). “It’s the same reason we can use money. When everyone believes in something’s value, we can use it for real things; money for food, and *p*-values for knowledge claims, publication, funding, and promotion. It doesn’t matter if the *p*-value doesn’t mean what people think it means; it becomes valuable because of what it buys.”

Goodman observes that statisticians alone cannot address the problem, and that “any approach involving only statisticians will not succeed.” He calls on statisticians to ally themselves “both with scientists in other fields and with broader based, multidisciplinary scientific reform movements. What statisticians can do within our own discipline is important, but to effectively disseminate or implement virtually any method or policy, we need partners.”

“The loci of influence,” Goodman says, “include journals, scientific lay and professional media (including social media), research funders, healthcare payors, technology assessors, regulators, academic institutions, the private sector, and professional societies. They also can include policy or informational entities like the National Academies...as well as various other science advisory bodies across the government. Increasingly, they are also including non-traditional science reform organizations comprised both of scientists and of the science literate lay public...and a broad base of health or science advocacy groups...”

It is no wonder, then, that the problem has persisted for so long. And persist it has! Hubbard (2019) looked at citation-count data on twenty-five articles and books severely critical of the effect of null hypothesis significance testing (NHST) on good science. Though issues were well known, Hubbard says, this did nothing to stem NHST usage over time.

Greenland (personal communication, January 25, 2019) notes that cognitive biases and perverse incentives to offer firm conclusions where none are warranted can warp the use of any method. “The core human and systemic problems are not addressed by shifting blame to p -values and pushing alternatives as magic cures—especially alternatives that have been subject to little or no comparative evaluation in either classrooms or practice,” Greenland said. “What we need now is to move beyond debating only our methods and their interpretations, to concrete proposals for elimination of systemic problems such as pressure to produce noteworthy findings rather than to produce reliable studies and analyses. Review and provisional acceptance of reports before their results are given to the journal (Locascio 2019) is one way to address that pressure, but more ideas are needed since review of promotions and funding applications cannot be so blinded. The challenges of how to deal with human biases and incentives may be the most difficult we must face.” Supporting this view is McShane and Gal’s (2016, 2017) empirical demonstration of cognitive dichotomization errors among biomedical and social science researchers—and even among statisticians.

Challenges for editors and reviewers are many. Here’s an example: Fricker et al. (2019) observed that when p -values were suspended from the journal *Basic and Applied Social Psychology* authors tended to overstate conclusions.

With all the challenges, how do we get from here to there, from a “ $p < 0.05$ ” world to a post “ $p < 0.05$ ” world?

Matthews (2019) notes that “Any proposal encouraging changes in inferential practice must accept the ubiquity of NHST...Pragmatism suggests, therefore, that the best hope of achieving a change in practice lies in offering inferential tools that can be used alongside the concepts of NHST, adding value to them while mitigating their most egregious features.”

Benjamin and Berger (2019) propose three practices to help researchers during the transition away from use of statistical significance. “[O]ur goal is to suggest minimal changes that would require little effort for the scientific community to implement,” they say. “Motivating this goal are our hope that easy (but impactful) changes might be adopted and our worry that more complicated changes could be resisted simply because they are perceived to be too difficult for routine implementation.”

Yet there is also concern that progress will stop after a small step or two. Even some proponents of small steps are clear that those small steps still carry us far short of the destination.

For example, Matthews (2019) says that his proposed methodology “is not a panacea for the inferential ills of the research community.” But that doesn’t make it useless. It may “encourage researchers to move beyond NHST and explore the statistical armamentarium now available to answer the central question of research: what does our study tell us?” he says. It “provides a bridge between the dominant but flawed NHST paradigm and the less familiar but more informative methods of Bayesian estimation.”

Likewise, Benjamin and Berger (2019) observe, “In research communities that are deeply attached to reliance on ‘ $p < 0.05$,’ our recommendations will serve as initial steps away from this attachment. We emphasize that our recommendations are intended merely as initial, temporary steps and that many

further steps will need to be taken to reach the ultimate destination: a holistic interpretation of statistical evidence that fully conforms to the principles laid out in the ASA Statement...”

Yet, like the authors of this editorial, not all authors in this special issue support gradual approaches with transitional methods.

Some (e.g., Amrhein, Trafimow, and Greenland 2019; Hurlbert, Levine, and Utts 2019; McShane et al. 2019) prefer to rip off the bandage and abandon use of statistical significance altogether. In short, no more dichotomizing p -values into categories of “significance.” Notably, these authors do not suggest banning the use of p -values, but rather suggest using them descriptively, treating them as continuous, and assessing their weight or import with nuanced thinking, clear language, and full understanding of their properties.

So even when there is agreement on the destination, there is disagreement about what road to take. The questions around reform need consideration and debate. It might turn out that different fields take different roads.

The catalyst for change may well come from those people who fund, use, or depend on scientific research, say Calin-Jageman and Cumming (2019). They believe this change has not yet happened to the desired level because of “the cognitive opacity of the NHST approach: the counter-intuitive p -value (it’s good when it is small), the mysterious null hypothesis (you want it to be false), and the eminently confusable Type I and Type II errors.”

Reviewers of this editorial asked, as some readers of it will, is a p -value threshold ever okay to use? We asked some of the authors of articles in the special issue that question as well. Authors identified four general instances. Some allowed that, while p -value thresholds should not be used for inference, they might still be useful for applications such as industrial quality control, in which a highly automated decision rule is needed and the costs of erroneous decisions can be carefully weighed when specifying the threshold. Other authors suggested that such dichotomized use of p -values was acceptable in model-fitting and variable selection strategies, again as automated tools, this time for sorting through large numbers of potential models or variables. Still others pointed out that p -values with very low thresholds are used in fields such as physics, genomics, and imaging as a filter for massive numbers of tests. The fourth instance can be described as “confirmatory setting[s] where the study design and statistical analysis plan are specified prior to data collection, and then adhered to during and after it” (Tong 2019). Tong argues these are the only proper settings for formal statistical inference. And Wellek (2017) says at present it is essential in these settings. “[B]inary decision making is indispensable in medicine and related fields,” he says. “[A] radical rejection of the classical principles of statistical inference...is of virtually no help as long as no conclusively substantiated alternative can be offered.”

Eliminating the declaration of “statistical significance” based on $p < 0.05$ or other arbitrary thresholds will be easier in some venues than others. Most journals, if they are willing, could fairly rapidly implement editorial policies to effect these changes. Suggestions for how to do that are in this special issue of *The American Statistician*. However, regulatory agencies might require longer timelines for making changes. The U.S. Food and

Drug Administration (FDA), for example, has long established drug review procedures that involve comparing p -values to significance thresholds for Phase III drug trials. Many factors demand consideration, not the least of which is how to avoid turning every drug decision into a court battle. Goodman (2019) cautions that, even as we seek change, “we must respect the reason why the statistical procedures are there in the first place.” Perhaps the ASA could convene a panel of experts, internal and external to FDA, to provide a workable new paradigm. (See Ruberg et al. 2019, who argue for a Bayesian approach that employs data from other trials as a “prior” for Phase 3 trials.)

Change is needed. Change has been needed for decades. Change has been called for by others for quite a while. So...

6. Why Will Change Finally Happen Now?

In 1991, a confluence of weather events created a monster storm that came to be known as “the perfect storm,” entering popular culture through a book (Junger 1997) and a 2000 movie starring George Clooney. Concerns about reproducible science, falling public confidence in science, and the initial impact of the ASA statement in heightening awareness of long-known problems created a perfect storm, in this case, a good storm of motivation to make lasting change. Indeed, such change was the intent of the ASA statement, and we expect this special issue of TAS will inject enough additional energy to the storm to make its impact widely felt.

We are not alone in this view. “60+ years of incisive criticism has not yet dethroned NHST as the dominant approach to inference in many fields of science,” note Calin-Jageman and Cumming (2019). “Momentum, though, seems to finally be on the side of reform.”

Goodman (2019) agrees: “The initial slow speed of progress should not be discouraging; that is how all broad-based social movements move forward and we should be playing the long game. But the ball is rolling downhill, the current generation is inspired and impatient to carry this forward.”

So, let’s do it. Let’s move beyond “statistically significant,” even if upheaval and disruption are inevitable for the time being. It’s worth it. In a world beyond “ $p < 0.05$,” by breaking free from the bonds of statistical significance, statistics in science and policy will become more significant than ever.

7. Authors’ Suggestions

The editors of this special TAS issue on statistical inference asked all the contact authors to help us summarize the guidance they provided in their papers by providing us a short list of do’s. We asked them to be specific but concise and to be active—start each with a verb. Here is the complete list of the authors’ responses, ordered as the papers appear in this special issue.

7.1. Getting to a Post “ $p < 0.05$ ” Era

Ioannidis, J., What Have We (Not) Learnt From Millions of Scientific Papers With p -Values?

1. Do not use p -values, unless you have clearly thought about the need to use them and they still seem the best choice.

2. Do not favor “statistically significant” results.
3. Do be highly skeptical about “statistically significant” results at the 0.05 level.

Goodman, S., Why Is Getting Rid of p -Values So Hard? Musings on Science and Statistics

1. Partner with science reform movements and reformers within disciplines, journals, funding agencies and regulators to promote and reward reproducible science and diminish the impact of statistical significance on publication, funding and promotion.
2. Speak to and write for the multifarious array of scientific disciplines, showing how statistical uncertainty and reasoning can be conveyed in non-“bright-line” ways both with conventional and alternative approaches. This should be done not just in didactic articles, but also in original or reanalyzed research, to demonstrate that it is publishable.
3. Promote, teach and conduct meta-research within many individual scientific disciplines to demonstrate the adverse effects in each of over-reliance on and misinterpretation of p -values and significance verdicts in individual studies and the benefits of emphasizing estimation and cumulative evidence.
4. Require reporting a quantitative measure of certainty—a “confidence index”—that an observed relationship, or claim, is true. Change analysis goal from achieving significance to appropriately estimating this confidence.
5. Develop and share teaching materials, software, and published case examples to help with all of the do’s above, and to spread progress in one discipline to others.

Hubbard, R., Will the ASA’s Efforts to Improve Statistical Practice be Successful? Some Evidence to the Contrary

This list applies to the ASA and to the professional statistics community more generally.

1. Specify, where/if possible, those situations in which the p -value plays a clearly valuable role in data analysis and interpretation.
2. Contemplate issuing a statement abandoning the use of p -values in null hypothesis significance testing.

Kmetz, J., Correcting Corrupt Research: Recommendations for the Profession to Stop Misuse of p -Values

1. Refer to the ASA statement on p -values whenever submitting a paper or revision to any editor, peer reviewer, or prospective reader. Many in the field do not know of this statement, and having the support of a prestigious organization when authoring any research document will help stop corrupt research from becoming even more dominant than it is.
2. Train graduate students and future researchers by having them reanalyze published studies and post their findings to appropriate websites or weblogs. This practice will benefit not only the students, but will benefit the professions, by increasing the amount of replicated (or nonreplicated) research available and readily accessible, and as well as reformer organizations that support replication.
3. Join one or more of the reformer organizations formed or forming in many research fields, and support and publicize their efforts to improve the quality of research practices.

4. Challenge editors and reviewers when they assert that incorrect practices and interpretations of research, consistent with existing null hypothesis significance testing and beliefs regarding p -values, should be followed in papers submitted to their journals. Point out that new submissions have been prepared to be consistent with the ASA statement on p -values.
5. Promote emphasis on research quality rather than research quantity in universities and other institutions where professional advancement depends heavily on research “productivity,” by following the practices recommended in this special journal edition. This recommendation will fall most heavily on those who have already achieved success in their fields, perhaps by following an approach quite different from that which led to their success; whatever the merits of that approach may have been, one objectionable outcome of it has been the production of voluminous corrupt research and creation of an environment that promotes and protects it. We must do better.

Hubbard, D., and Carriquiry, A., *Quality Control for Scientific Research: Addressing Reproducibility, Responsiveness and Reliance*

1. Compute and prominently display the probability the hypothesis is true (or a probability distribution of an effect size) or provide sufficient information for future researchers and policy makers to compute it.
2. Promote publicly displayed quality control metrics within your field—in particular, support tracking of reproduction studies and computing the “level 1” and even “level 2” priors as required for #1 above.
3. Promote a byline status for researchers who reproduce studies: Digital versions are dynamically updated to display “Reproduced by...” below original research authors’ names or “Not yet reproduced” until it is reproduced.

Brownstein, N., Louis, T., O’Hagan, A., and Pendergast, J., *The Role of Expert Judgment in Statistical Inference and Evidence-Based Decision-Making*

1. Staff the study team with members who have the necessary knowledge, skills and experience—statistically, scientifically, and otherwise.
2. Include key members of the research team, including statisticians, in all scientific and administrative meetings.
3. Understand that subjective judgments are needed in all stages of a study.
4. Make all judgments as carefully and rigorously as possible and document each decision and rationale for transparency and reproducibility.
5. Use protocol-guided elicitation of judgments.
6. Statisticians specifically should:
 - Refine oral and written communication skills.
 - Understand their multiple roles and obligations as collaborators.
 - Take an active leadership role as a member of the scientific team; contribute throughout all phases of the study.

- Co-own the subject matter—understand a sufficient amount about the relevant science/policy to meld statistical and subject-area expertise.
- Promote the expectation that your collaborators co-own statistical issues.
- Write a statistical analysis plan for all analyses and track any changes to that plan over time.
- Promote co-responsibility for data quality, security, and documentation.
- Reduce unplanned and uncontrolled modeling/testing (HARK-ing, p -hacking); document all analyses.

O’Hagan, A., *Expert Knowledge Elicitation: Subjective but Scientific*

1. Elicit expert knowledge when data relating to a parameter of interest is weak, ambiguous or indirect.
2. Use a well-designed protocol, such as SHELF, to ensure expert knowledge is elicited in as scientific and unbiased a way as possible.

Kennedy-Shaffer, L., *Before $p < 0.05$ to Beyond $p < 0.05$: Using History to Contextualize p -Values and Significance Testing*

1. Ensure that inference methods match intuitive understandings of statistical reasoning.
2. Reduce the computational burden for nonstatisticians using statistical methods.
3. Consider changing conditions of statistical and scientific inference in developing statistical methods.
4. Address uncertainty quantitatively and in ways that reward increased precision.

Hubbard, R., Haig, B. D., and Parsa, R. A., *The Limited Role of Formal Statistical Inference in Scientific Inference*

1. Teach readers that although deemed equivalent in the social, management, and biomedical sciences, formal methods of statistical inference and scientific inference are very different animals.
2. Show these readers that formal methods of statistical inference play only a restricted role in scientific inference.
3. Instruct researchers to pursue significant *sameness* (i.e., replicable and empirically generalizable results) rather than significant *differences* in results.
4. Demonstrate how the pursuit of significant differences actively impedes cumulative knowledge development.

McShane, B., Tackett, J., Böckenholt, U., and Gelman, A., *Large Scale Replication Projects in Contemporary Psychological Research*

1. When planning a replication study of a given psychological phenomenon, bear in mind that replication is complicated in psychological research because studies can never be direct or exact replications of one another, and thus heterogeneity—effect sizes that vary from one study of the phenomenon to the next—cannot be avoided.
2. Future large scale replication projects should follow the “one phenomenon, many studies” approach of the Many Labs project and Registered Replication Reports rather than the

“many phenomena, one study” approach of the Open Science Collaboration project. In doing so, they should systematically vary method factors across the laboratories involved in the project.

3. Researchers analyzing the data resulting from large scale replication projects should do so via a hierarchical (or multi-level) model fit to the totality of the individual-level observations. In doing so, all theoretical moderators should be modeled via covariates while all other potential moderators—that is, method factors—should induce variation (i.e., heterogeneity).
4. Assessments of replicability should not depend solely on estimates of effects, or worse, significance tests based on them. Heterogeneity must also be an important consideration in assessing replicability.

7.2. Interpreting and Using p

Greenland, S., *Valid p -Values Behave Exactly as They Should: Some Misleading Criticisms of p -Values and Their Resolution With s -Values*

1. Replace any statements about statistical significance of a result with the p -value from the test, and present the p -value as an equality, not an inequality. For example, if $p = 0.03$ then “...was statistically significant” would be replaced by “...had $p = 0.03$,” and “ $p < 0.05$ ” would be replaced by “ $p = 0.03$.” (An exception: If p is so small that the accuracy becomes very poor then an inequality reflecting that limit is appropriate; e.g., depending on the sample size, p -values from normal or χ^2 approximations to discrete data often lack even 1-digit accuracy when $p < 0.0001$.) In parallel, if $p = 0.25$ then “...was not statistically significant” would be replaced by “...had $p = 0.25$,” and “ $p > 0.05$ ” would be replaced by “ $p = 0.25$.”
2. Present p -values for more than one possibility when testing a targeted parameter. For example, if you discuss the p -value from a test of a null hypothesis, also discuss alongside this null p -value another p -value for a plausible alternative parameter possibility (ideally the one used to calculate power in the study proposal). As another example: if you do an equivalence test, present the p -values for both the lower and upper bounds of the equivalence interval (which are used for equivalence tests based on two one-sided tests).
3. Show confidence intervals for targeted study parameters, but also supplement them with p -values for testing relevant hypotheses (e.g., the p -values for both the null and the alternative hypotheses used for the study design or proposal, as in #2). Confidence intervals only show clearly what is in or out of the interval (i.e., a 95% interval only shows clearly what has $p > 0.05$ or $p \leq 0.05$), but more detail is often desirable for key hypotheses under contention.
4. Compare groups and studies directly by showing p -values and interval estimates for their differences, not by comparing p -values or interval estimates from the two groups or studies. For example, seeing $p = 0.03$ in males and $p = 0.12$ in females does **not** mean that different associations were seen in males and females; instead, one needs a p -value and confidence interval for the difference in the sex-specific

associations to examine the between-sex difference. Similarly, if an early study reported a confidence interval which excluded the null and then a subsequent study reported a confidence interval which included the null, that does not mean the studies gave conflicting results or that the second study failed to replicate the first study; instead, one needs a p -value and confidence interval for the difference in the study-specific associations to examine the between-study difference. In all cases, differences-between-differences must be analyzed directly by statistics for that purpose.

5. Supplement a focal p -value p with its Shannon information transform (s -value or surprisal) $s = -\log_2(p)$. This measures the amount of information supplied by the test against the tested hypothesis (or model): Rounded off, the s -value s shows the number of heads in a row one would need to see when tossing a coin to get the same amount of information against the tosses being “fair” (independent with “heads” probability of $1/2$) instead of being loaded for heads. For example, if $p = 0.03$, this represents $-\log_2(0.03) = 5$ bits of information against the hypothesis (like getting 5 heads in a trial of “fairness” with 5 coin tosses); and if $p = 0.25$, this represents only $-\log_2(0.25) = 2$ bits of information against the hypothesis (like getting 2 heads in a trial of “fairness” with only 2 coin tosses).

Betensky, R., *The p -Value Requires Context, Not a Threshold*

1. Interpret the p -value in light of its context of sample size and meaningful effect size.
2. Incorporate the sample size and meaningful effect size into a decision to reject the null hypothesis.

Anderson, A., *Assessing Statistical Results: Magnitude, Precision and Model Uncertainty*

1. Evaluate the importance of statistical results based on their practical implications.
2. Evaluate the strength of empirical evidence based on the precision of the estimates and the plausibility of the modeling choices.
3. Seek out subject matter expertise when evaluating the importance and the strength of empirical evidence.

Heck, P., and Krueger, J., *Putting the p -Value in Its Place*

1. Use the p -value as a heuristic, that is, as the base for a tentative inference regarding the presence or absence of evidence against the tested hypothesis.
2. Supplement the p -value with other, conceptually distinct methods and practices, such as effect size estimates, likelihood ratios, or graphical representations.
3. Strive to embed statistical hypothesis testing within strong *a priori* theory and a context of relevant prior empirical evidence.

Johnson, V., *Evidence From Marginally Significant t -Statistics*

1. Be transparent in the number of outcome variables that were analyzed.
2. Report the number (and values) of all test statistics that were calculated.
3. Provide access to protocols for studies involving human or animal subjects.

- Clearly describe data values that were excluded from analysis and the justification for doing so.
- Provide sufficient details on experimental design so that other researchers can replicate the experiment.
- Describe only p -values less than 0.005 as being “statistically significant.”

Fraser, D., *The p -Value Function and Statistical Inference*

- Determine a primary variable for assessing the hypothesis at issue.
- Calculate its well defined distribution function, respecting continuity.
- Substitute the observed data value to obtain the “ p -value function.”
- Extract the available well defined confidence bounds, confidence intervals, and median estimate.
- Know that you don’t have an intellectual basis for decisions.

Rougier, J., *p -Values, Bayes Factors, and Sufficiency*

- Recognize that behind every choice of null distribution and test statistic, there lurks a plausible family of alternative hypotheses, which can provide more insight into the null distribution.

Rose, S., and McGuire, T., *Limitations of p -Values and R -Squared for Stepwise Regression Building: A Fairness Demonstration in Health Policy Risk Adjustment*

- Formulate a clear objective for variable inclusion in regression procedures.
- Assess all relevant evaluation metrics.
- Incorporate algorithmic fairness considerations.

7.3. Supplementing or Replacing p

Blume, J., Greevy, R., Welty, V., Smith, J., and DuPont, W., *An Introduction to Second Generation p -Values*

- Construct a composite null hypothesis by specifying the range of effects that are not scientifically meaningful (do this before looking at the data). Why: Eliminating the conflict between scientific significance and statistical significance has numerous statistical and scientific benefits.
- Replace classical p -values with second-generation p -values (SGPV). Why: SGPVs accommodate composite null hypotheses and encourage the proper communication of findings.
- Interpret the SGPV as a high-level summary of what the data say. Why: Science needs a simple indicator of when the data support only meaningful effects (SGPV = 0), when the data support only trivially null effects (SGPV = 1), or when the data are inconclusive ($0 < \text{SGPV} < 1$).
- Report an interval estimate of effect size (confidence interval, support interval, or credible interval) and note its proximity to the composite null hypothesis. Why: This is a more detailed description of study findings.
- Consider reporting false discovery rates with SGPVs of 0 or 1. Why: FDRs gauge the chance that an inference is incorrect under assumptions about the data generating process and prior knowledge.

Goodman, W., Spruill, S., and Komaroff, E., *A Proposed Hybrid Effect Size Plus p -Value Criterion: Empirical Evidence Supporting Its Use*

- Determine how far the true parameter’s value would have to be, in your research context, from exactly equaling the conventional, point null hypothesis to consider that the distance is meaningfully large or practically significant.
- Combine the conventional p -value criterion with a minimum effect size criterion to generate a two-criteria inference-indicator signal, which provides heuristic, but nondefinitive evidence, for inferring the parameter’s true location.
- Document the intended criteria for your inference procedures, such as a p -value cut-point and a minimum practically significant effect size, prior to undertaking the procedure.
- Ensure that you use the appropriate inference method for the data that are obtainable and for the inference that is intended.
- Acknowledge that every study is fraught with limitations from unknowns regarding true data distributions and other conditions that one’s method assumes.

Benjamin, D., and Berger, J., *Three Recommendations for Improving the Use of p -Values*

- Replace the 0.05 “statistical significance” threshold for claims of novel discoveries with a 0.005 threshold and refer to p -values between 0.05 and 0.005 as “suggestive.”
- Report the data-based odds of the alternative hypothesis to the null hypothesis. If the data-based odds cannot be calculated, then use the p -value to report an upper bound on the data-based odds: $1/(-ep \ln p)$.
- Report your prior odds and posterior odds (prior odds * data-based odds) of the alternative hypothesis to the null hypothesis. If the data-based odds cannot be calculated, then use your prior odds and the p -value to report an upper bound on your posterior odds: (prior odds) * $(1/(-ep \ln p))$.

Colquhoun, D., *The False Positive Risk: A Proposal Concerning What to Do About p -Values*

- Continue to provide p -values and confidence intervals. Although widely misinterpreted, people know how to calculate them and they aren’t entirely useless. Just don’t ever use the terms “statistically significant” or “nonsignificant.”
- Provide in addition an indication of false positive risk (FPR). This is the probability that the claim of a real effect on the basis of the p -value is in fact false. The FPR (not the p -value) is the probability that your result occurred by chance. For example, the fact that, under plausible assumptions, observation of a p -value close to 0.05 corresponds to an FPR of at least 0.2–0.3 shows clearly the weakness of the conventional criterion for “statistical significance.”
- Alternatively, specify the prior probability of there being a real effect that one would need to be able to justify in order to achieve an FPR of, say, 0.05.

Notes:

There are many ways to calculate the FPR. One, based on a point null and simple alternative can be calculated with the web calculator at <http://fpr-calc.ucl.ac.uk/>. However other approaches to the calculation of FPR, based on different

assumptions, give results that are similar (Table 1 in Colquhoun 2019).

To calculate FPR it is necessary to specify a prior probability and this is rarely known. My recommendation 2 is based on giving the FPR for a prior probability of 0.5. Any higher prior probability of there being a real effect is not justifiable in the absence of hard data. In this sense, the calculated FPR is the minimum that can be expected. More implausible hypotheses would make the problem worse. For example, if the prior probability of there being a real effect were only 0.1, then observation of $p = 0.05$ would imply a disastrously high $FPR = 0.76$, and in order to achieve an FPR of 0.05, you'd need to observe $p = 0.00045$. Others (especially Goodman) have advocated giving likelihood ratios (LRs) in place of p -values. The FPR for a prior of 0.5 is simply $1/(1 + LR)$, so to give the FPR for a prior of 0.5 is simply a more-easily-comprehensible way of specifying the LR, and so should be acceptable to frequentists and Bayesians.

Matthews, R., *Moving Toward the Post $p < 0.05$ Era via the Analysis of Credibility*

1. Report the outcome of studies as effect sizes summarized by confidence intervals (CIs) along with their point estimates.
2. Make full use of the point estimate and width and location of the CI relative to the null effect line when interpreting findings. The point estimate is generally the effect size best supported by the study, irrespective of its statistical significance/nonsignificance. Similarly, tight CIs located far from the null effect line generally represent more compelling evidence for a nonzero effect than wide CIs lying close to that line.
3. Use the analysis of credibility (AnCred) to assess quantitatively the credibility of inferences based on the CI. AnCred determines the level of prior evidence needed for a new finding to provide credible evidence for a nonzero effect.
4. Establish whether this required level of prior evidence is supported by current knowledge and insight. If it is, the new result provides credible evidence for a nonzero effect, irrespective of its statistical significance/nonsignificance.

Gannon, M., Pereira, C., and Polpo, A., *Blending Bayesian and Classical Tools to Define Optimal Sample-Size-Dependent Significance Levels*

1. Retain the useful concept of statistical significance and the same operational procedures as currently used for hypothesis tests, whether frequentist (Neyman–Pearson p -value tests) or Bayesian (Bayes-factor tests).
2. Use tests with a sample-size-dependent significance level—ours is optimal in the sense of the generalized Neyman–Pearson lemma.
3. Use a testing scheme that allows tests of any kind of hypothesis, without restrictions on the dimensionalities of the parameter space or the hypothesis. Note that this should include “sharp” hypotheses, which correspond to subsets of lower dimensionality than the full parameter space.
4. Use hypothesis tests that are compatible with the likelihood principle (LP). They can be easier to interpret consistently than tests that are not LP-compliant.

5. Use numerical methods to handle hypothesis-testing problems with high-dimensional sample spaces or parameter spaces.

Pogrow, S., *How Effect Size (Practical Significance) Misleads Clinical Practice: The Case for Switching to Practical Benefit to Assess Applied Research Findings*

1. Switch from reliance on statistical or practical significance to the more stringent statistical criterion of practical benefit for (a) assessing whether applied research findings indicate that an intervention is effective and should be adopted and scaled—particularly in complex organizations such as schools and hospitals and (b) determining whether relationships are sufficiently strong and explanatory to be used as a basis for setting policy or practice recommendations. Practical benefit increases the likelihood that observed benefits will replicate in subsequent research and in clinical practice by avoiding the problems associated with relying on small effect sizes.
2. Reform statistics courses in applied disciplines to include the principles of practical benefit, and have students review influential applied research articles in the discipline to determine which findings demonstrate practical benefit.
3. Recognize the need to develop different inferential statistical criteria for assessing the importance of applied research findings as compared to assessing basic research findings.
4. Consider consistent, noticeable improvements across contexts using the quick prototyping methods of improvement science as a preferable methodology for identifying effective practices rather than on relying on RCT methods.
5. Require that applied research reveal the actual unadjusted means/medians of results for all groups and subgroups, and that review panels take such data into account—as opposed to only reporting relative differences between adjusted means/medians. This will help preliminarily identify whether there appear to be clear benefits for an intervention.

7.4. Adopting More Holistic Approaches

McShane, B., Gal, D., Gelman, A., Robert, C., and Tackett, J., *Abandon Statistical Significance*

1. Treat p -values (and other purely statistical measures like confidence intervals and Bayes factors) continuously rather than in a dichotomous or thresholded manner. In doing so, bear in mind that it seldom makes sense to calibrate evidence as a function of p -values or other purely statistical measures because they are, among other things, typically defined relative to the generally uninteresting and implausible null hypothesis of zero effect and zero systematic error.
2. Give consideration to related prior evidence, plausibility of mechanism, study design and data quality, real world costs and benefits, novelty of finding, and other factors that vary by research domain. Do this always—not just once some p -value or other statistical threshold has been attained—and do this without giving priority to p -values or other purely statistical measures.

3. Analyze and report all of the data and relevant results rather than focusing on single comparisons that attain some p -value or other statistical threshold.
4. Conduct a decision analysis: p -value and other statistical threshold-based rules implicitly express a particular tradeoff between Type I and Type II error, but in reality this tradeoff should depend on the costs, benefits, and probabilities of all outcomes.
5. Accept uncertainty and embrace variation in effects: we can learn much (indeed, more) about the world by forsaking the false promise of certainty offered by dichotomous declarations of truth or falsity—binary statements about there being “an effect” or “no effect”—based on some p -value or other statistical threshold being attained.
6. Obtain more precise individual-level measurements, use within-person or longitudinal designs more often, and give increased consideration to models that use informative priors, that feature varying treatment effects, and that are multilevel or meta-analytic in nature.

Tong, C., *Statistical Inference Enables Bad Science; Statistical Thinking Enables Good Science*

1. Prioritize effort for sound data production: the planning, design, and execution of the study.
2. Build scientific arguments with many sets of data and multiple lines of evidence.
3. Recognize the difference between exploratory and confirmatory objectives and use distinct statistical strategies for each.
4. Use flexible descriptive methodology, including disciplined data exploration, enlightened data display, and regularized, robust, and nonparametric models, for exploratory research.
5. Restrict statistical inferences to confirmatory analyses for which the study design and statistical analysis plan are pre-specified prior to, and strictly adhered to during, data acquisition.

Amrhein, V., Trafimow, D., and Greenland, S., *Inferential Statistics as Descriptive Statistics: There Is No Replication Crisis If We Don't Expect Replication*

1. Do not dichotomize, but embrace variation.
 - (a) Report and interpret inferential statistics like the p -value in a continuous fashion; do not use the word “significant.”
 - (b) Interpret interval estimates as “compatibility intervals,” showing effect sizes most compatible with the data, under the model used to compute the interval; do not focus on whether such intervals include or exclude zero.
 - (c) Treat inferential statistics as highly unstable local descriptions of relations between models and the obtained data.
 - (i) Free your “negative results” by allowing them to be potentially positive. Most studies with large p -values or interval estimates that include the null should be considered “positive,” in the sense that they usually leave open the possibility of important effects (e.g., the effect sizes within the interval estimates).

- (ii) Free your “positive results” by allowing them to be different. Most studies with small p -values or interval estimates that are not near the null should be considered provisional, because in replication studies the p -values could be large and the interval estimates could show very different effect sizes.
- (iii) There is no replication crisis if we don't expect replication. Honestly reported results *must* vary from replication to replication because of varying assumption violations and random variation; excessive agreement itself would suggest deeper problems such as failure to publish results in conflict with group expectations.

Calin-Jageman, R., and Cumming, G., *The New Statistics for Better Science: Ask How Much, How Uncertain, and What Else Is Known*

1. Ask quantitative questions and give quantitative answers.
2. Countenance uncertainty in all statistical conclusions, seeking ways to quantify, visualize, and interpret the potential for error.
3. Seek replication, and use quantitative methods to synthesize across data sets as a matter of course.
4. Use Open Science practices to enhance the trustworthiness of research results.
5. Avoid, wherever possible, any use of p -values or NHST.

Ziliak, S., *How Large Are Your G-Values? Try Gosset's Guinnessometrics When a Little “p” Is Not Enough*

- *G-10 Consider the Purpose of the Inquiry, and Compare with Best Practice.* Falsification of a null hypothesis is not the main purpose of the experiment or observational study. Making money or beer or medicine—ideally more and better than the competition and best practice—is. Estimating the importance of your coefficient relative to results reported by others, is. To repeat, as the 2016 ASA Statement makes clear, merely falsifying a null hypothesis with a qualitative yes/no, exists/does not exist, significant/not significant answer, is not itself significant science, and should be eschewed.
- *G-9 Estimate the Stakes (Or Eat Them).* Estimation of magnitudes of effects, and demonstrations of their substantive meaning, should be the center of most inquiries. Failure to specify the stakes of a hypothesis is the first step toward eating them (gulp).
- *G-8 Study Correlated Data: ABBA, Take a Chance on Me.* Most regression models assume “iid” error terms— independently and identically distributed—yet most data in the social and life sciences are correlated by systematic, nonrandom effects—and are thus not independent. Gosset solved the problem of correlated soil plots with the “ABBA” layout, maximizing the correlation of paired differences between the As and Bs with a perfectly balanced chiasmic arrangement.
- *G-7 Minimize “Real Error” with the 3 R's: Represent, Replicate, Reproduce.* A test of significance on a single set of data is nearly valueless. Fisher's p , Student's t , and other tests should only be used when there is actual repetition of the experi-

ment. “One and done” is scientism, not scientific. Random error is not equal to real error, and is usually smaller and less important than the sum of nonrandom errors. Measurement error, confounding, specification error, and bias of the auspices are frequently larger in all the testing sciences, agronomy to medicine. Guinnessometrics minimizes real error by repeating trials on stratified and balanced yet independent experimental units, controlling as much as possible for local fixed effects.

- *G-6 Economize with “Less is More”: Small Samples of Independent Experiments.* Small sample analysis and distribution theory has an economic origin and foundation: changing inputs to the beer on the large scale (for Guinness, enormous global scale) is risky, with more than money at stake. But smaller samples, as Gosset showed in decades of barley and hops experimentation, does not mean “less than,” and Big Data is in any case not the solution for many problems.
- *G-5 Keep Your Eyes on the Size Matters/How Much? Question.* There will be distractions but the expected loss and profit functions rule, or should. Are regression coefficients or differences between means large or small? Compared to what? How do you know?
- *G-4 Visualize.* Parameter uncertainty is not the same thing as model uncertainty. Does the result hit you between the eyes? Does the study show magnitudes of effects across the entire distribution? Advances in visualization software continue to outstrip advances in statistical modeling, making more visualization a no brainer.
- *G-3 Consider Posteriors and Priors too (“It pays to go Bayes”).* The sample on hand is rarely the only thing that is “known.” Subject matter expertise is an important prior input to statistical design and affects analysis of “posterior” results. For example, Gosset at Guinness was wise to keep quality assurance metrics and bottom line profit at the center of his inquiry. How does prior information fit into the story and evidence? Advances in Bayesian computing software make it easier and easier to do a Bayesian analysis, merging prior and posterior information, values, and knowledge.
- *G-2 Cooperate Up, Down, and Across (Networks and Value Chains).* For example, where would brewers be today without the continued cooperation of farmers? Perhaps back on the farm and not at the brewery making beer. Statistical science is social, and cooperation helps. Guinness financed a large share of modern statistical theory, and not only by supporting Gosset and other brewers with academic sabbaticals (Ziliak and McCloskey 2008).
- *G-1 Answer the Brewer’s Original Question (“How should you set the odds?”).* No bright-line rule of statistical significance can answer the brewer’s question. As Gosset said way back in 1904, how you set the odds depends on “the importance of the issues at stake” (e.g., the expected benefit and cost) together with the cost of obtaining new material.

Billheimer, D., *Predictive Inference and Scientific Reproducibility*

1. Predict observable events or quantities that you care about.
2. Quantify the uncertainty of your predictions.

Manski, C., *Treatment Choice With Trial Data: Statistical Decision Theory Should Supplant Hypothesis Testing*

1. Statisticians should relearn statistical decision theory, which received considerable attention in the middle of the twentieth century but was largely forgotten by the century’s end.
2. Statistical decision theory should supplant hypothesis testing when statisticians study treatment choice with trial data.
3. Statisticians should use statistical decision theory when analyzing decision making with sample data more generally.

Manski, C., and Tetenov, A., *Trial Size for Near Optimal Choice between Surveillance and Aggressive Treatment: Reconsidering MSLT-II*

1. Statisticians should relearn statistical decision theory, which received considerable attention in the middle of the twentieth century but was largely forgotten by the century’s end.
2. Statistical decision theory should supplant hypothesis testing when statisticians study treatment choice with trial data.
3. Statisticians should use statistical decision theory when analyzing decision making with sample data more generally.

Lavine, M., *Frequentist, Bayes, or Other?*

1. Look for and present results from many models that fit the data well.
2. Evaluate models, not just procedures.

Ruberg, S., Harrell, F., Gamalo-Siebers, M., LaVange, L., Lee J., Price K., and Peck C., *Inference and Decision-Making for 21st Century Drug Development and Approval*

1. Apply Bayesian paradigm as a framework for improving statistical inference and regulatory decision making by using probability assertions about the magnitude of a treatment effect.
2. Incorporate prior data and available information formally into the analysis of the confirmatory trials.
3. Justify and pre-specify how priors are derived and perform sensitivity analysis for a better understanding of the impact of the choice of prior distribution.
4. Employ quantitative utility functions to reflect key considerations from all stakeholders for optimal decisions via a probability-based evaluation of the treatment effects.
5. Intensify training in Bayesian approaches, particularly for decision makers and clinical trialists (e.g., physician scientists in FDA, industry and academia).

van Dongen, N., Wagenmakers, E.J., van Doorn, J., Gronau, Q., van Ravenzwaaij, D., Hoekstra, R., Haucke, M., Lakens, D., Hennig, C., Morey, R., Homer, S., Gelman, A., and Sprenger, J., *Multiple Perspectives on Inference for Two Simple Statistical Scenarios*

1. Clarify your statistical goals explicitly and unambiguously.
2. Consider the question of interest and choose a statistical approach accordingly.
3. Acknowledge the uncertainty in your statistical conclusions.
4. Explore the robustness of your conclusions by executing several different analyses.
5. Provide enough background information such that other researchers can interpret your results and possibly execute meaningful alternative analyses.

7.5. Reforming Institutions: Changing Publication Policies and Statistical Education

Trafimow, D., *Five Nonobvious Changes in Editorial Practice for Editors and Reviewers to Consider When Evaluating Submissions in a Post $P < 0.05$ Universe*

1. Tolerate ambiguity.
2. Replace significance testing with a priori thinking.
3. Consider the nature of the contribution, on multiple levels.
4. Emphasize thinking and execution, not results.
5. Consider that the assumption of random and independent sampling might be wrong.

Locascio, J., *The Impact of Results Blind Science Publishing on Statistical Consultation and Collaboration*

For journal reviewers

1. Provide an initial provisional decision regarding acceptance for publication of a journal manuscript based exclusively on the judged importance of the research issues addressed by the study and the soundness of the reported methodology. (The latter would include appropriateness of data analysis methods.) Give no weight to the reported results of the study per se in the decision as to whether to publish or not.
2. To ensure #1 above is accomplished, commit to an initial decision regarding publication after having been provided with only the Introduction and Methods sections of a manuscript by the editor, not having seen the Abstract, Results, or Discussion. (The latter would be reviewed only if and after a generally irrevocable decision to publish has already been made.)

For investigators/manuscript authors

1. Obtain consultation and collaboration from statistical consultant(s) and research methodologist(s) early in the development and conduct of a research study.
2. Emphasize the clinical and scientific importance of a study in the Introduction section of a manuscript, and give a clear, explicit statement of the research questions being addressed and any hypotheses to be tested.
3. Include a detailed statistical analysis subsection in the Methods section, which would contain, among other things, a justification of the adequacy of the sample size and the reasons various statistical methods were employed. For example, if null hypothesis significance testing and p -values are used, presumably supplemental to other methods, justify why those methods apply and will provide useful additional information in this particular study.
4. Submit for publication reports of well-conducted studies on important research issues regardless of findings, for example, even if only null effects were obtained, hypotheses were not confirmed, mere replication of previous results were found, or results were inconsistent with established theories.

Hurlbert, S., Levine, R., and Utts, J., *Coup de Grâce for a Tough Old Bull: "Statistically Significant" Expires*

1. Encourage journal editorial boards to disallow use of the phrase "statistically significant," or even "significant," in manuscripts they will accept for review.

2. Give primary emphasis in abstracts to the magnitudes of those effects most conclusively demonstrated and of greatest import to the subject matter.
3. Report precise p -values or other indices of evidence against null hypotheses as continuous variables not requiring any labeling.
4. Understand the meaning of and rationale for neoFisherian significance assessment (NFSA).

Campbell, H., and Gustafson, P., *The World of Research Has Gone Berserk: Modeling the Consequences of Requiring "Greater Statistical Stringency" for Scientific Publication*

1. Consider the meta-research implications of implementing new publication/funding policies. Journal editors and research funders should attempt to model the impact of proposed policy changes before any implementation. In this way, we can anticipate the policy impacts (both positive and negative) on the types of studies researchers pursue and the types of scientific articles that ultimately end up published in the literature.

Fricker, R., Burke, K., Han, X., and Woodall, W., *Assessing the Statistical Analyses Used in Basic and Applied Social Psychology After Their p -Value Ban*

1. Use measures of statistical significance combined with measures of practical significance, such as confidence intervals on effect sizes, in assessing research results.
2. Classify research results as either exploratory or confirmatory and appropriately describe them as such in all published documentation.
3. Define precisely the population of interest in research studies and carefully assess whether the data being analyzed are representative of the population.
4. Understand the limitations of inferential methods applied to observational, convenience, or other nonprobabilistically sampled data.

Maurer, K., Hudiburgh, L., Werwinski, L., and Bailer J., *Content Audit for p -Value Principles in Introductory Statistics*

1. Evaluate the coverage of p -value principles in the introductory statistics course using rubrics or other systematic assessment guidelines.
2. Discuss and deploy improvements to curriculum coverage of p -value principles.
3. Meet with representatives from other departments, who have majors taking your statistics courses, to make sure that inference is being taught in a way that fits the needs of their disciplines.
4. Ensure that the correct interpretation of p -value principles is a point of emphasis for all faculty members and embedded within all courses of instruction.

Steel, A., Liermann, M., and Guttorp, P., *Beyond Calculations: A Course in Statistical Thinking*

1. Design curricula to teach students how statistical analyses are embedded within a larger science life-cycle, including steps such as project formulation, exploratory graphing, peer review, and communication beyond scientists.
2. Teach the p -value as only one aspect of a complete data analysis.

3. Prioritize helping students build a strong understanding of what testing and estimation can tell you over teaching statistical procedures.
4. Explicitly teach statistical communication. Effective communication requires that students clearly formulate the benefits and limitations of statistical results.
5. Force students to struggle with poorly defined questions and real, messy data in statistics classes.
5. Encourage students to match the mathematical metric (or data summary) to the scientific question. Teaching students to create customized statistical tests for custom metrics allows statistics to move beyond the mean and pinpoint specific scientific questions.

Acknowledgments

Without the help of a huge team, this special issue would never have happened. The articles herein are about the equivalent of three regular issues of *The American Statistician*. Thank you to all the authors who submitted papers for this issue. Thank you, authors whose papers were accepted, for enduring our critiques. We hope they made you happier with your finished product. Thank you to a talented, hard-working group of associate editors for handling many papers: Frank Bretz, George Cobb, Doug Hubbard, Ray Hubbard, Michael Lavine, Fan Li, Xihong Lin, Tom Louis, Regina Nuzzo, Jane Pendergast, Annie Qu, Sherri Rose, and Steve Ziliak. Thank you to all who served as reviewers. We definitely couldn't have done this without you. Thank you, TAS Editor Dan Jeske, for your vision and your willingness to let us create this special issue. Special thanks to Janet Wallace, TAS editorial coordinator, for spectacular work and tons of patience. We also are grateful to ASA Journals Manager Eric Sampson for his leadership, and to our partners, the team at Taylor and Francis, for their commitment to ASA's publishing efforts. Thank you to all who read and commented on the draft of this editorial. You made it so much better! Regina Nuzzo provided extraordinarily helpful substantive and editorial comments. And thanks most especially to the ASA Board of Directors, for generously and enthusiastically supporting the "p-values project" since its inception in 2014. Thank you for your leadership of our profession and our association.

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Exhibit 138

COMMENT

EVOLUTION Cooperation and conflict from ants and chimps to us **p.308**

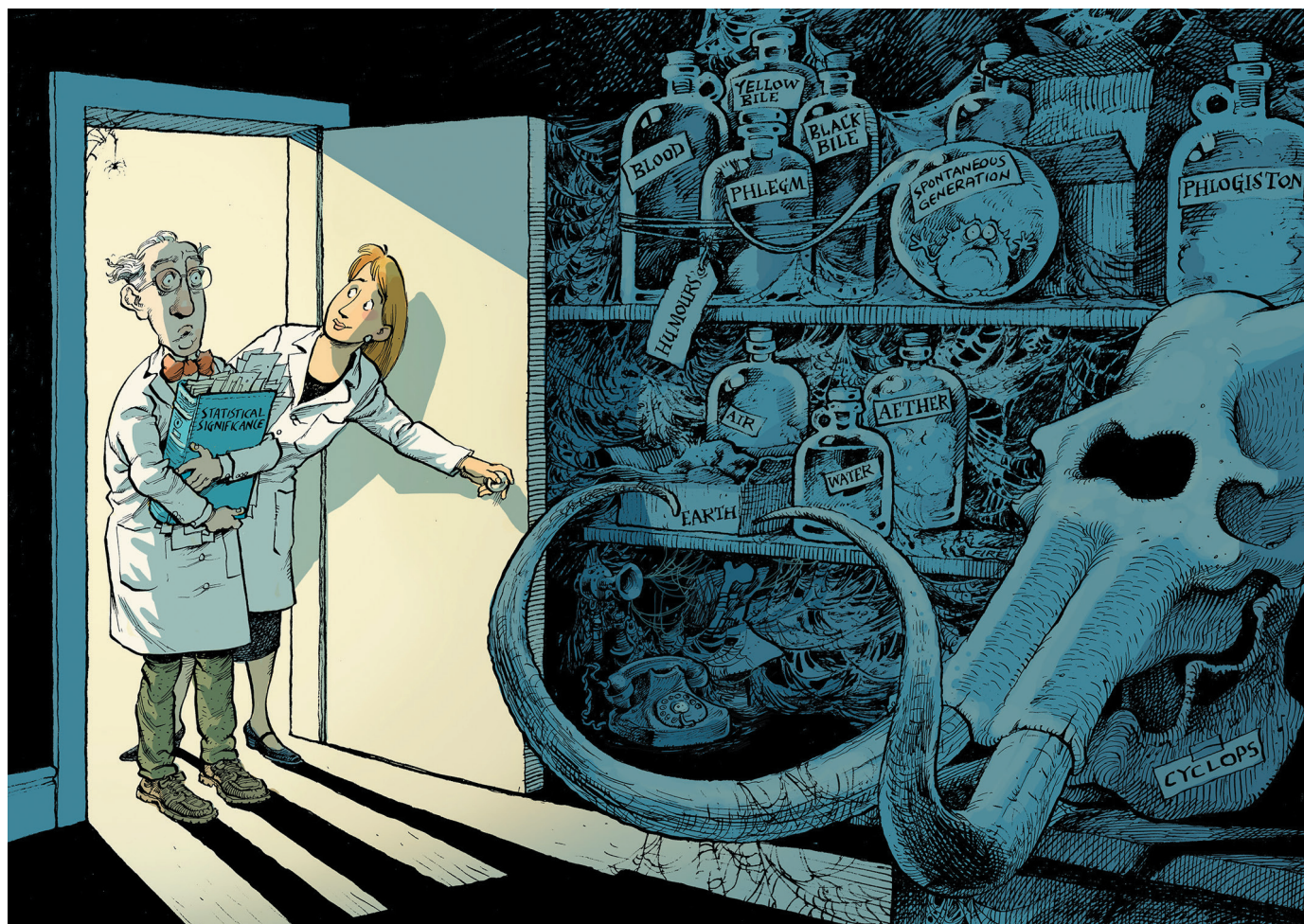


HISTORY To fight denial, study Galileo and Arendt **p.309**

CHEMISTRY Three more unsung women — of astatine discovery **p.311**

PUBLISHING As well as ORCID ID and English, list authors in their own script **p.311**

ILLUSTRATION BY DAVID PARKINS



Retire statistical significance

Valentin Amrhein, Sander Greenland, Blake McShane and more than 800 signatories call for an end to hyped claims and the dismissal of possibly crucial effects.

When was the last time you heard a seminar speaker claim there was ‘no difference’ between two groups because the difference was ‘statistically non-significant’?

If your experience matches ours, there’s a good chance that this happened at the last talk you attended. We hope that at least someone in the audience was perplexed if, as frequently happens, a plot or table showed that there actually was a difference.

How do statistics so often lead scientists to deny differences that those not educated in statistics can plainly see? For several generations, researchers have been warned that a statistically non-significant result does not ‘prove’ the null hypothesis (the hypothesis that there is no difference between groups or no effect of a treatment on some measured outcome)¹. Nor do statistically significant results ‘prove’ some other hypothesis. Such misconceptions have famously warped the

literature with overstated claims and, less famously, led to claims of conflicts between studies where none exists.

We have some proposals to keep scientists from falling prey to these misconceptions.

PERVASIVE PROBLEM

Let’s be clear about what must stop: we should never conclude there is ‘no difference’ or ‘no association’ just because a *P* value is larger than a threshold such as 0.05 ►

► or, equivalently, because a confidence interval includes zero. Neither should we conclude that two studies conflict because one had a statistically significant result and the other did not. These errors waste research efforts and misinform policy decisions.

For example, consider a series of analyses of unintended effects of anti-inflammatory drugs². Because their results were statistically non-significant, one set of researchers concluded that exposure to the drugs was “not associated” with new-onset atrial fibrillation (the most common disturbance to heart rhythm) and that the results stood in contrast to those from an earlier study with a statistically significant outcome.

Now, let's look at the actual data. The researchers describing their statistically non-significant results found a risk ratio of 1.2 (that is, a 20% greater risk in exposed patients relative to unexposed ones). They also found a 95% confidence interval that spanned everything from a trifling risk decrease of 3% to a considerable risk increase of 48% ($P = 0.091$; our calculation). The researchers from the earlier, statistically significant, study found the exact same risk ratio of 1.2. That study was simply more precise, with an interval spanning from 9% to 33% greater risk ($P = 0.0003$; our calculation).

It is ludicrous to conclude that the statistically non-significant results showed “no association”, when the interval estimate included serious risk increases; it is equally absurd to claim these results were in contrast with the earlier results showing an identical observed effect. Yet these common practices show how reliance on thresholds of statistical significance can mislead us (see ‘Beware false conclusions’).

These and similar errors are widespread. Surveys of hundreds of articles have found that statistically non-significant results are interpreted as indicating ‘no difference’ or ‘no effect’ in around half (see ‘Wrong interpretations’ and Supplementary Information).

In 2016, the American Statistical

Association released a statement in *The American Statistician* warning against the misuse of statistical significance and P values. The issue also included many commentaries on the subject. This month, a special issue in the same journal attempts to push these reforms further. It presents more than 40 papers on ‘Statistical inference in the 21st century: a world beyond $P < 0.05$ ’. The editors introduce the collection with the caution “don't say ‘statistically significant’”³. Another article⁴ with dozens of signatories also calls on authors and journal editors to disavow those terms.

We agree, and call for the entire concept of statistical significance to be abandoned.

“Eradicating categorization will help to halt overconfident claims, unwarranted declarations of ‘no difference’ and absurd statements about ‘replication failure’.”

We are far from alone. When we invited others to read a draft of this comment and sign their names if they concurred with our message, 250 did so within the first 24 hours. A week later, we had more than 800 signatories — all checked for an academic affiliation or other indication of present or past work in a field that depends on statistical modeling (see the list and final count of signatories in the Supplementary Information). These include statisticians, clinical and medical researchers, biologists and psychologists from more than 50 countries and across all continents except Antarctica. One advocate called it a “surgical strike against thoughtless testing of statistical significance” and “an opportunity to register your voice in favour of better scientific practices”.

We are not calling for a ban on P values. Nor are we saying they cannot be used as a decision criterion in certain specialized applications (such as determining whether a manufacturing process meets

some quality-control standard). And we are also not advocating for an anything-goes situation, in which weak evidence suddenly becomes credible. Rather, and in line with many others over the decades, we are calling for a stop to the use of P values in the conventional, dichotomous way — to decide whether a result refutes or supports a scientific hypothesis⁵.

QUIT CATEGORIZING

The trouble is human and cognitive more than it is statistical: bucketing results into ‘statistically significant’ and ‘statistically non-significant’ makes people think that the items assigned in that way are categorically different^{6–8}. The same problems are likely to arise under any proposed statistical alternative that involves dichotomization, whether frequentist, Bayesian or otherwise.

Unfortunately, the false belief that crossing the threshold of statistical significance is enough to show that a result is ‘real’ has led scientists and journal editors to privilege such results, thereby distorting the literature. Statistically significant estimates are biased upwards in magnitude and potentially to a large degree, whereas statistically non-significant estimates are biased downwards in magnitude. Consequently, any discussion that focuses on estimates chosen for their significance will be biased. On top of this, the rigid focus on statistical significance encourages researchers to choose data and methods that yield statistical significance for some desired (or simply publishable) result, or that yield statistical non-significance for an undesired result, such as potential side effects of drugs — thereby invalidating conclusions.

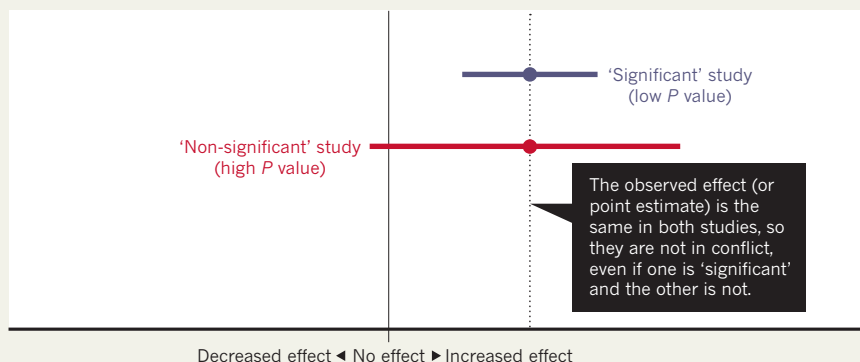
The pre-registration of studies and a commitment to publish all results of all analyses can do much to mitigate these issues. However, even results from pre-registered studies can be biased by decisions invariably left open in the analysis plan⁹. This occurs even with the best of intentions.

Again, we are not advocating a ban on P values, confidence intervals or other statistical measures — only that we should not treat them categorically. This includes dichotomization as statistically significant or not, as well as categorization based on other statistical measures such as Bayes factors.

One reason to avoid such ‘dichotomania’ is that all statistics, including P values and confidence intervals, naturally vary from study to study, and often do so to a surprising degree. In fact, random variation alone can easily lead to large disparities in P values, far beyond falling just to either side of the 0.05 threshold. For example, even if researchers could conduct two perfect replication studies of some genuine effect, each with 80% power (chance) of achieving $P < 0.05$, it would not be very surprising for one to obtain $P < 0.01$ and the other $P > 0.30$.

BEWARE FALSE CONCLUSIONS

Studies currently dubbed ‘statistically significant’ and ‘statistically non-significant’ need not be contradictory, and such designations might cause genuine effects to be dismissed.



SOURCE: V. AMRHEIN ET AL

SOURCE: V. AMRHEIN ET AL.

Whether a P value is small or large, caution is warranted.

We must learn to embrace uncertainty. One practical way to do so is to rename confidence intervals as ‘compatibility intervals’ and interpret them in a way that avoids overconfidence. Specifically, we recommend that authors describe the practical implications of all values inside the interval, especially the observed effect (or point estimate) and the limits. In doing so, they should remember that all the values between the interval’s limits are reasonably compatible with the data, given the statistical assumptions used to compute the interval^{7,10}. Therefore, singling out one particular value (such as the null value) in the interval as ‘shown’ makes no sense.

We’re frankly sick of seeing such nonsensical ‘proofs of the null’ and claims of non-association in presentations, research articles, reviews and instructional materials. An interval that contains the null value will often also contain non-null values of high practical importance. That said, if you deem all of the values inside the interval to be practically unimportant, you might then be able to say something like ‘our results are most compatible with no important effect’.

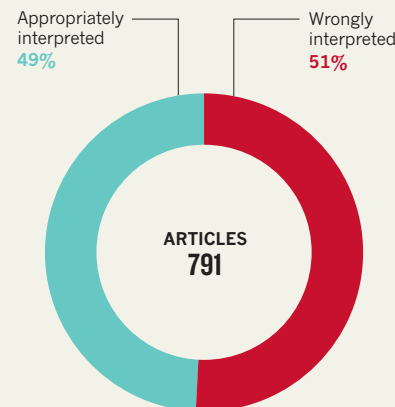
When talking about compatibility intervals, bear in mind four things. First, just because the interval gives the values most compatible with the data, given the assumptions, it doesn’t mean values outside it are incompatible; they are just less compatible. In fact, values just outside the interval do not differ substantively from those just inside the interval. It is thus wrong to claim that an interval shows all possible values.

Second, not all values inside are equally compatible with the data, given the assumptions. The point estimate is the most compatible, and values near it are more compatible than those near the limits. This is why we urge authors to discuss the point estimate, even when they have a large P value or a wide interval, as well as discussing the limits of that interval. For example, the authors above could have written: ‘Like a previous study, our results suggest a 20% increase in risk of new-onset atrial fibrillation in patients given the anti-inflammatory drugs. Nonetheless, a risk difference ranging from a 3% decrease, a small negative association, to a 48% increase, a substantial positive association, is also reasonably compatible with our data, given our assumptions.’ Interpreting the point estimate, while acknowledging its uncertainty, will keep you from making false declarations of ‘no difference’, and from making overconfident claims.

Third, like the 0.05 threshold from which it came, the default 95% used to compute intervals is itself an arbitrary convention. It is based on the false idea that there is a 95% chance that the computed interval itself contains the true value, coupled with the vague

WRONG INTERPRETATIONS

An analysis of 791 articles across 5 journals* found that around half mistakenly assume non-significance means no effect.



*Data taken from: P. Schatz et al. *Arch. Clin. Neuropsychol.* **20**, 1053–1059 (2005); F. Fidler et al. *Consens. Biol.* **20**, 1539–1544 (2006); R. Hoekstra et al. *Psychon. Bull. Rev.* **13**, 1033–1037 (2006); F. Bernardi et al. *Eur. Sociol. Rev.* **33**, 1–15 (2017).

feeling that this is a basis for a confident decision. A different level can be justified, depending on the application. And, as in the anti-inflammatory-drugs example, interval estimates can perpetuate the problems of statistical significance when the dichotomization they impose is treated as a scientific standard.

Last, and most important of all, be humble: compatibility assessments hinge on the correctness of the statistical assumptions used to compute the interval. In practice, these assumptions are at best subject to considerable uncertainty^{7,8,10}. Make these assumptions as clear as possible and test the ones you can, for example by plotting your data and by fitting alternative models, and then reporting all results.

Whatever the statistics show, it is fine to suggest reasons for your results, but discuss a range of potential explanations, not just favoured ones. Inferences should be scientific, and that goes far beyond the merely statistical. Factors such as background evidence, study design, data quality and understanding of underlying mechanisms are often more important than statistical measures such as P values or intervals.

The objection we hear most against retiring statistical significance is that it is needed to make yes-or-no decisions. But for the choices often required in regulatory, policy and business environments, decisions based on the costs, benefits and likelihoods of all potential consequences always beat those made based solely on statistical significance. Moreover, for decisions about whether to pursue a research idea further, there is no simple connection between a P value and the probable results of subsequent studies.

What will retiring statistical significance look like? We hope that methods sections

and data tabulation will be more detailed and nuanced. Authors will emphasize their estimates and the uncertainty in them — for example, by explicitly discussing the lower and upper limits of their intervals. They will not rely on significance tests. When P values are reported, they will be given with sensible precision (for example, $P = 0.021$ or $P = 0.13$) — without adornments such as stars or letters to denote statistical significance and not as binary inequalities ($P < 0.05$ or $P > 0.05$). Decisions to interpret or to publish results will not be based on statistical thresholds. People will spend less time with statistical software, and more time thinking.

Our call to retire statistical significance and to use confidence intervals as compatibility intervals is not a panacea. Although it will eliminate many bad practices, it could well introduce new ones. Thus, monitoring the literature for statistical abuses should be an ongoing priority for the scientific community. But eradicating categorization will help to halt overconfident claims, unwarranted declarations of ‘no difference’ and absurd statements about ‘replication failure’ when the results from the original and replication studies are highly compatible. The misuse of statistical significance has done much harm to the scientific community and those who rely on scientific advice. P values, intervals and other statistical measures all have their place, but it’s time for statistical significance to go. ■

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Sander Greenland is a professor of epidemiology and statistics at the University of California, Los Angeles. **Blake McShane** is a statistical methodologist and professor of marketing at Northwestern University in Evanston, Illinois. For a full list of co-signatories, see *Supplementary Information*.

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Supplementary information accompanies this article; see go.nature.com/2tc5nm

Exhibit 139

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF NEW JERSEY

3 -----x

4 IN RE: JOHNSON & JOHNSON TALCUM

5 POWDER PRODUCTS MARKETING, SALES

6 PRACTICES, AND PRODUCTS MDL NO:

7 LIABILITY LITIGATION 16-2738 (FLW)(LHG)

8 -----x

9 THIS DOCUMENT RELATES TO

10 ALL CASES

11 -----x

12

13

14 DEPOSITION UNDER ORAL EXAMINATION OF

15 SARAH E. KANE, M.D.

16 January 25, 2019, 9:19 a.m.

17

18 - - -

19 REPORTED BY: JANET M. SAMBATARO, RMR, CRR, CLR

20 - - -

21 GOLKOW TECHNOLOGIES, INC.

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25

Sarah E. Kane, M.D.

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<p>1 2 3 4 5 6 7 Deposition of SARAHE. KANE, M.D., 8 held at the offices of Sugarman, Rogers, 9 Barshak & Cohen, PC 363 Plantation Street, Boston, 10 Massachusetts, pursuant to Agreement before 11 Janet Sambataro, a Registered Merit Reporter, 12 Certified Realtime Reporter, Certified LiveNote 13 Reporter, and a Notary Public within and for the 14 Commonwealth of Massachusetts, on January 25, 2019, 15 commencing at 9:19 a.m. 16 17 18 19 20 21 22 23 24 25</p>	<p>1 APPEARANCES: (Continued) 2 3 SHOOK, HARDY & BACON L.L.P. 4 BY: HUNTER K. AHERN, ESQ. 5 701 Fifth Avenue, Suite 6800 6 Seattle, Washington 98104 7 (206) 344-7600 8 hahern@shb.com 9 Representing the Defendant, Johnson & Johnson, 10 Johnson & Johnson Consumer Companies, Inc. 11 12 DRINKER BIDDLE AND REATH LLP 13 BY: KATHERINE MCBETH, ESQ. 14 One Logan Square, Suite 2000 15 Philadelphia, Pennsylvania 19103-6996 16 (215) 988-2700 17 katherine.mcbeth@dbr.com 18 Representing the Defendant, Johnson & Johnson, 19 Johnson & Johnson Consumer Companies, Inc. 20 21 GORDON & REES SCULLY MANSUKHANI, LLP 22 BY: MICHAEL R. KLATT, ESQUIRE 23 816 Congress Avenue, Suite 1510 24 Austin, Texas 78701 25 (512) 391-0197</p>
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Sarah E. Kane, M.D.

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<p>1 EXHIBITS</p> <p>2 Number Description Page</p> <p>3 Exhibit 25 (Continued)</p> <p>4 and ovarian talc particle burden" 308</p> <p>5 Exhibit 26 Article entitled "Pycnogenol reduces</p> <p>6 Talc-induced Neoplastic Transformation</p> <p>7 in Human Ovarian Cell Cultures" 328</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 identified yesterday in that list are voluminous</p> <p>2 and dense and require additional time to cover,</p> <p>3 to the extent that they substantively informed</p> <p>4 Dr. Kane's opinions in this case.</p> <p>5 We'd also like to object to the</p> <p>6 inclusion of those materials on the science day</p> <p>7 presentations, which were not intended for any</p> <p>8 other purpose than for science day in the MDL.</p> <p>9 And that's all I have to say on the</p> <p>10 objections.</p> <p>11 MR. ROTMAN: Go ahead.</p> <p>12 MR. TISI: First of all, as you know,</p> <p>13 many of those documents were documents that were</p> <p>14 provided to counsel in connection with virtually</p> <p>15 every depositions that have been taken to date.</p> <p>16 In fact, it was provided with Dr. Mohrman that</p> <p>17 was being taken at the same time today; it was</p> <p>18 provided with Dr. Zelikoff earlier in the week;</p> <p>19 it was provided almost routinely.</p> <p>20 Many of them -- some of them,</p> <p>21 particularly the Health Canada document, were</p> <p>22 documents that only became available in mid</p> <p>23 December, number one.</p> <p>24 Number two, I believe that the science</p> <p>25 day document that you're referring to, which I</p>
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<p>1 PROCEEDINGS</p> <p>2 THE VIDEOGRAPHER: We are now on the</p> <p>3 record. My name is Jody Urbati. I am a</p> <p>4 videographer for Golkow Litigation Services.</p> <p>5 Today's date is January 25, 2019; the time,</p> <p>6 9:19 a.m.</p> <p>7 This video deposition is being held in</p> <p>8 Boston, Massachusetts, In Re: Johnson & Johnson</p> <p>9 Talcum Powder Products Liability Litigation in</p> <p>10 the United States District Court for the District</p> <p>11 of New Jersey.</p> <p>12 The deponent today is Sarah Kane.</p> <p>13 Counsel will be noted on the stenographic record.</p> <p>14 The court reporter is Janet Sambataro and will</p> <p>15 now swear in the witness.</p> <p>16 (Witness sworn.)</p> <p>17 MS. AHERN: Just a quick housekeeping</p> <p>18 matter. The defendants would like to lodge an</p> <p>19 objection to the additional materials to Sarah</p> <p>20 Kane that were served yesterday at 3:36 p.m. by</p> <p>21 Ashcraft law firm. Serving supplementary</p> <p>22 materials 24 hours before an expert deposition is</p> <p>23 prejudicial to the defendants' ability to</p> <p>24 prepare.</p> <p>25 The number of the documents that were</p>	<p>1 think you'll find was not relied on in any way,</p> <p>2 was a -- that was the California and not the MDL.</p> <p>3 So I just want to be clear about that.</p> <p>4 So there is no prejudice, and we would</p> <p>5 clearly object to -- these are not documents she</p> <p>6 relied on for her report; they just are</p> <p>7 supplemental materials. But -- you can ask</p> <p>8 questions, but we will certainly object to</p> <p>9 reconvening the deposition at any later time. We</p> <p>10 made that clear yesterday.</p> <p>11 MS. AHERN: Thank you.</p> <p>12 MR. ROTMAN: Yeah, there was -- one of</p> <p>13 the documents was a textbook that Dr. Kane first</p> <p>14 looked at two days ago or -- yeah, I think it was</p> <p>15 two days ago, and so I added it to the list. And</p> <p>16 she brought the textbook with her today.</p> <p>17 MR. KLATT: Can I just add we had an</p> <p>18 agreement for all the other depositions, and I</p> <p>19 assume we continue today, one objection by a</p> <p>20 party is good for all.</p> <p>21 MR. TISI: That's fine, yes.</p> <p>22 MR. ROTMAN: And, you know, just so</p> <p>23 it's clear to anybody reading the transcript that</p> <p>24 what you received yesterday was the third</p> <p>25 reference list that we've provided for Dr. Kane,</p>

Sarah E. Kane, M.D.

<p style="text-align: right;">Page 14</p> <p>1 the first being with her report in November; the 2 second being on January 4th, which was about ten 3 days before the deposition had been scheduled for 4 January 14th; and then these additional items 5 were materials that either were inadvertently 6 left off or not reviewed until just very 7 recently.</p> <p>8 MS. AHERN: Okay. To the extent that 9 these new materials inform her substantive 10 opinions and were not included in her report or 11 prior versions of the reference list, then we can 12 talk about that later --</p> <p>13 MR. TISI: Yeah.</p> <p>14 MS. AHERN: -- in terms of additional 15 time.</p> <p>16 And just to clarify, Steve, you said 17 that she reviewed one textbook. It looks like on 18 the list that I received, she reviewed the 19 second, fourth, and fifth editions of the 20 textbook --</p> <p>21 MR. ROTMAN: I was referring --</p> <p>22 MS. AHERN: -- or textbooks.</p> <p>23 MR. ROTMAN: I was referring to that as 24 one textbook, yeah, but you're right, the 25 different editions. And she did bring with her</p>	<p style="text-align: right;">Page 16</p> <p>1 Commonwealth Pathology Partners? 2 A. The address we commonly use is 81 3 Highland Avenue, Salem, Massachusetts. It's 4 01970.</p> <p>5 Q. Okay. And do you have any separate 6 consulting business?</p> <p>7 A. No. Other -- outside of this type of 8 medical expert witness work, no.</p> <p>9 Q. Okay. And how often do you do this 10 sort of medical witness work?</p> <p>11 A. I am very new at it. I have done one 12 deposition before in a tobacco case.</p> <p>13 Q. Okay. And the fees that you get from 14 these cases, do they go directly to you or do 15 they go to your -- Commonwealth Pathology 16 Partners?</p> <p>17 A. They go directly to me.</p> <p>18 Q. And, Dr. Kane, you're a medical doctor; 19 correct?</p> <p>20 A. Yes.</p> <p>21 Q. And what is your medical specialty?</p> <p>22 A. I am board certified in anatomic and 23 clinical pathology and cytopathology, with 24 fellowship training in gynecologic pathology.</p> <p>25 Q. Does that mean that you review</p>
<p style="text-align: right;">Page 15</p> <p>1 today those materials.</p> <p>2 MS. AHERN: So she has a copy with her 3 today of all of the items listed in the 4 additional materials to Sarah Kane that was 5 served yesterday.</p> <p>6 MR. ROTMAN: No.</p> <p>7 MS. AHERN: Okay. Do you know what 8 she -- well, we can -- we'll find out.</p> <p>9 MR. ROTMAN: Yeah.</p> <p>10 MS. AHERN: Okay. All right.</p> <p>11 SARAH E. KANE, M.D., 12 having been duly sworn, after presenting 13 identification in the form of a driver's license, 14 deposes and says as follows:</p> <p>15 DIRECT EXAMINATION</p> <p>16 BY MS. AHERN:</p> <p>17 Q. Good morning, Dr. Kane.</p> <p>18 A. Good morning.</p> <p>19 Q. Can you please state your name for the 20 record?</p> <p>21 A. Sure. Sarah Kane.</p> <p>22 Q. And, Dr. Kane, who is your current 23 employer?</p> <p>24 A. Commonwealth Pathology Partners.</p> <p>25 Q. And do you have a business address at</p>	<p style="text-align: right;">Page 17</p> <p>1 diagnostic materials, slides, and blocks that 2 have been taken from patient procedures and make 3 determinations regarding diagnosis?</p> <p>4 A. Yes.</p> <p>5 Q. Do you see patients as part of your 6 medical practice?</p> <p>7 A. Yes. Occasionally, cytopathologists 8 sometimes perform a procedure that's called a 9 fine-needle aspiration. And so if a patient is 10 seen in clinic and the clinician discovers a 11 palpable nodule, I might be asked to go into the 12 room and perform a fine-needle aspiration.</p> <p>13 Q. But you don't see patients in the sense 14 that you don't counsel patients and provide 15 ongoing care for an individual patient?</p> <p>16 A. Well, I mean, I guess my pathology 17 report is part of the -- basically speaks to 18 medical treatment and informs clinical treatment 19 of the patient. So my pathology reports are seen 20 by the patient.</p> <p>21 Q. I guess what I'm getting at is: Do you 22 see patients as part of your practice, give them 23 a history and physical, provide ongoing care for 24 them outside of the setting of a fine-needle 25 aspiration or a specific procedure related to a</p>

<p style="text-align: right;">Page 18</p> <p>1 diagnosis?</p> <p>2 MR. ROTMAN: Is this working for you?</p> <p>3 THE WITNESS: Oh, I'm sorry?</p> <p>4 MR. ROTMAN: Is it working?</p> <p>5 THE WITNESS: Yes.</p> <p>6 MR. ROTMAN: Okay.</p> <p>7 A. Outside of the fine-needle aspiration</p> <p>8 setting, the only time I might see a patient</p> <p>9 would be with a blood transfusion reaction. I</p> <p>10 might have to go to the floor to examine the</p> <p>11 patient or patient chart.</p> <p>12 Ongoing care for them outside of the setting</p> <p>13 of a fine-needle aspiration, the nature of</p> <p>14 gynecologic pathology, sometimes I will see a Pap</p> <p>15 smear from a patient and then a cervical biopsy</p> <p>16 from a patient and then a LEEP from the patient,</p> <p>17 and I might speak to the clinician about</p> <p>18 treatment algorithms, that kind of thing.</p> <p>19 Q. Do you actually then go see the patient</p> <p>20 themselves and discuss with them the results of</p> <p>21 their Pap smear or other testing?</p> <p>22 A. Typically, no.</p> <p>23 Q. Have you ever performed a history and</p> <p>24 physical in your practice as a pathologist?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 20</p> <p>1 aspiration, a blood transfusion reaction.</p> <p>2 Are there any others?</p> <p>3 A. I'm trying to think what another</p> <p>4 possibility might be.</p> <p>5 I mean, I go into the operative room when</p> <p>6 patients are in surgery sometimes with the</p> <p>7 surgeon to do intraoperative frozen sections,</p> <p>8 which are realtime diagnosis while the patient is</p> <p>9 having a procedure.</p> <p>10 Q. But you're interacting with the</p> <p>11 physicians in that respect, aren't you, not with</p> <p>12 the patient?</p> <p>13 A. It can be both.</p> <p>14 MR. ROTMAN: Objection. Objection.</p> <p>15 You can answer.</p> <p>16 MS. AHERN: You can answer.</p> <p>17 A. The vast majority of the time I'm with</p> <p>18 frozen sections, I'm interacting with the</p> <p>19 surgeon.</p> <p>20 Q. Are there times where you are</p> <p>21 interacting with the patient during a surgical</p> <p>22 procedure?</p> <p>23 MR. ROTMAN: When you say</p> <p>24 "interacting," you mean having a conversation or</p> <p>25 do you mean having any kind of contact?</p>
<p style="text-align: right;">Page 19</p> <p>1 Q. Under what circumstances?</p> <p>2 A. Under blood transfusion reactions.</p> <p>3 Q. And what sort of history and physical</p> <p>4 do you take in relation to a blood transfusion</p> <p>5 reaction?</p> <p>6 A. Well, you might be looking at blood</p> <p>7 pressure and review of the medical chart,</p> <p>8 temperature, that kind of thing.</p> <p>9 Q. So you review the medical chart.</p> <p>10 Is that medical chart prepared by another</p> <p>11 physician?</p> <p>12 A. Usually, you're looking at</p> <p>13 retrospective data at the time of the blood</p> <p>14 transfusion reaction.</p> <p>15 Q. How often will you see the same patient</p> <p>16 who has had a blood transfusion reaction?</p> <p>17 A. Not very often.</p> <p>18 Q. Okay. Do you ever counsel patients on</p> <p>19 risk factors for ovarian cancer?</p> <p>20 A. Have I ever? Probably, but in my</p> <p>21 day-to-day practice, I'm not seeing patients on a</p> <p>22 regular basis to do that.</p> <p>23 Q. And the only time you see patients is</p> <p>24 with regard to specific issues that are within</p> <p>25 your realm of pathology expertise, a fine-needle</p>	<p style="text-align: right;">Page 21</p> <p>1 MR. KLATT: Steve, just limit the</p> <p>2 objection to "form."</p> <p>3 MR. ROTMAN: I'm trying to clarify.</p> <p>4 MR. KLATT: It doesn't matter.</p> <p>5 BY MS. AHERN:</p> <p>6 Q. Did you understand --</p> <p>7 MR. KLATT: Object to form.</p> <p>8 Q. -- the question, Doctor?</p> <p>9 A. Let me -- can -- I'm sorry. Can you</p> <p>10 read it back or --</p> <p>11 Q. You said, "The vast majority of" --</p> <p>12 MR. ROTMAN: She's reading, I think.</p> <p>13 MS. AHERN: I'll withdraw the question</p> <p>14 and just remind you.</p> <p>15 BY MS. AHERN:</p> <p>16 Q. You said that the vast majority of the</p> <p>17 time you're interacting with the physicians;</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. What do you mean by "interacting"?</p> <p>21 A. During the surgery, the surgeon might</p> <p>22 have me come up to the operative room or the</p> <p>23 surgeon might come down to look at the tissue,</p> <p>24 both grossly and under the microscope with me.</p> <p>25 Q. Okay. Under those circumstances, would</p>

<p style="text-align: right;">Page 22</p> <p>1 you ever speak to the patient?</p> <p>2 A. Usually not.</p> <p>3 Q. And if you -- have you ever spoken to a</p> <p>4 patient when you were reviewing frozen sections?</p> <p>5 A. I might have during rapid reads of</p> <p>6 fine-needle aspirations. So sometimes</p> <p>7 interventional radiologists will do fine-needle</p> <p>8 aspirations if they have to be ultrasound guided.</p> <p>9 So, yes, I'm speaking to patients sometimes in</p> <p>10 that situation and, obviously, when I do</p> <p>11 fine-needle aspirations.</p> <p>12 Q. Okay. But you don't have a group of</p> <p>13 patients that come to you for ongoing care and</p> <p>14 see you in an office setting, do you?</p> <p>15 A. They are basically -- I would say it's</p> <p>16 the equivalent of physician referral. So if a --</p> <p>17 if a clinician is doing a biopsy -- I mentioned</p> <p>18 women with Pap smears and then cervical biopsies</p> <p>19 and then cone LEEPs, you know, it's a trajectory</p> <p>20 of care, but it's physician referred for tissue.</p> <p>21 Q. When you say "physician referred," what</p> <p>22 do you -- what do you mean by that? Are you</p> <p>23 interacting with the physician in providing</p> <p>24 advice or recommendations or are you interacting</p> <p>25 with the patients themselves and providing advice</p>	<p style="text-align: right;">Page 24</p> <p>1 A. That's correct. They're not scheduled</p> <p>2 to see me.</p> <p>3 Q. Okay. And so outside of, like you</p> <p>4 mentioned, procedures like a fine-needle</p> <p>5 aspiration, you wouldn't generally see patients</p> <p>6 directly.</p> <p>7 A. The fine-needle aspiration would be the</p> <p>8 only setting where they would have a scheduled,</p> <p>9 allotted slot time with me.</p> <p>10 Q. Okay. Generally speaking, when you're</p> <p>11 reviewing slides, what sort of medical records do</p> <p>12 you have available to you that are relevant to</p> <p>13 your clinical diagnosis?</p> <p>14 A. I have the entire medical record</p> <p>15 available to me, whatever is in the hospital</p> <p>16 system for that patient.</p> <p>17 Q. What do you routinely rely on or review</p> <p>18 as part of your review of slides in terms of</p> <p>19 medical records?</p> <p>20 A. Well, it's very patient dependent and</p> <p>21 very diagnosis dependent, but, for example --</p> <p>22 I'll stick to the example of cervical biopsy. So</p> <p>23 I'll be looking -- if I have a cervical biopsy,</p> <p>24 I'll look to see the patient's history of Pap</p> <p>25 smears, HPV tests, that kind of thing.</p>
<p style="text-align: right;">Page 23</p> <p>1 or recommendations?</p> <p>2 A. The physicians usually.</p> <p>3 Q. Okay. So I'm asking about patients.</p> <p>4 A. Yeah.</p> <p>5 Q. On a given day -- like what are -- what</p> <p>6 are the days that you're in the office?</p> <p>7 A. Monday through Friday.</p> <p>8 Q. So are there days that you do</p> <p>9 particular tasks, administrative, and then days</p> <p>10 that you do frozen sections or days that you do</p> <p>11 just general pathology reads?</p> <p>12 A. Rarely, I have an administrative day.</p> <p>13 It would be nice to have more, but, typically, I</p> <p>14 am looking at slides the majority of the day.</p> <p>15 I will be doing frozen sections on some</p> <p>16 days, but we have a very collegial atmosphere, so</p> <p>17 I might do frozens with another pathologist.</p> <p>18 Some days I'm on cytology, so I'm doing the</p> <p>19 fine-needle aspirations, which is either me</p> <p>20 performing the fine-needle aspirations or me</p> <p>21 reading a rapid interpretation that an</p> <p>22 interventional radiologist has performed.</p> <p>23 Q. So on -- in a given week, it's not like</p> <p>24 you have a patient clinic where patients come to</p> <p>25 see you and they're scheduled to see you.</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. Documents that are directly relevant to</p> <p>2 your review of the current pathology; is that</p> <p>3 correct?</p> <p>4 A. For the most part, I would say so.</p> <p>5 Q. In other words, you don't go back</p> <p>6 through all of their physician records or</p> <p>7 gynecologic visits, their primary care physician</p> <p>8 records?</p> <p>9 A. Again, it would depend on the</p> <p>10 situation. I mean, if I have a lung tumor case,</p> <p>11 I'll probably be looking at the radiology, the</p> <p>12 radiology reports, the -- I'll pull up a report</p> <p>13 with a primary care physician to look for smoking</p> <p>14 history, that kind of thing, to put the whole</p> <p>15 piece together for the diagnosis.</p> <p>16 Q. Okay. And, Doctor, you're here today</p> <p>17 to provide a deposition as an expert witness on</p> <p>18 behalf of the plaintiffs; is that correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you said you've given one</p> <p>21 deposition in the past?</p> <p>22 A. Yes, that's correct.</p> <p>23 Q. And what sort of case was that?</p> <p>24 A. That was a tobacco case.</p> <p>25 Q. Were you an expert in that case?</p>

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<p style="text-align: right;">Page 26</p> <p>1 A. Yes. It was an individual causation 2 case. 3 Q. Okay. Were you an expert for the 4 plaintiffs or the defendants? 5 A. For the plaintiffs. 6 Q. And what sort of -- what sort of case 7 was that in terms of the injury that was being 8 alleged? 9 A. It was a patient with lung cancer who 10 was suing a tobacco company. 11 Q. And what was your specific -- what was 12 your opinion in that case? 13 A. That it was highly likely that her long 14 history of smoking caused her lung cancer. 15 Q. So -- and I should have gone over this 16 with you in the beginning, but you're familiar 17 with the deposition rules? 18 A. In general, I think. 19 Q. Okay. You're doing a very good job. 20 And the main things to remember is the two of us 21 will try not to speak over each other so that the 22 court reporter can take a clean transcript down. 23 If you need a break at some time, that's 24 fine, just let me know. All I ask is if there's 25 a question pending, you go ahead and finish the</p>	<p style="text-align: right;">Page 28</p> <p>1 MS. AHERN: You're welcome. 2 BY MS. AHERN: 3 Q. Dr. Kane, I've handed you a copy of 4 your Notice of Deposition for today. 5 Have you seen this document before? 6 A. Yes. 7 Q. When did you see it? 8 A. I believe it was sometime in December, 9 because the original deposition date was 10 January 14th. 11 Q. And, Doctor, do you know whether you 12 produced all of the documents that are responsive 13 to the request in Exhibit 1, your deposition 14 notice? 15 MR. ROTMAN: We've objected to a number 16 of them. And so she's producing -- you should go 17 item by item, I think, if you want to -- I'm 18 going to object otherwise. 19 Q. Doctor, do you know what you brought 20 with you today? 21 A. Yes. We have my -- a copy of my 22 updated CV. We have copies of my invoice. I 23 believe I have a copy of -- oh, right. Sorry. 24 I have pages that I found for the Blaustein 25 second edition, which I don't have the actual</p>
<p style="text-align: right;">Page 27</p> <p>1 answer to the question and then we'll take a 2 break. 3 If you don't understand a question that I 4 ask you, please don't answer it. Let me know 5 that you don't understand the question or you'd 6 like me to rephrase it and I'll be happy to do 7 that. All right? 8 A. Okay. 9 Q. Okay. And if you answer the question, 10 is it fair for me to assume that you understood 11 it? 12 A. Yes. 13 Q. All right. 14 (Notice of Oral and Videotaped 15 Deposition of Sarah E. Kane and Duces Tecum 16 marked Exhibit 1.) 17 BY MS. AHERN: 18 Q. Doctor, I'm handing you what's been 19 marked as Exhibit No. 1 to your deposition. 20 MS. AHERN: I don't know how many 21 people need copies of these. I don't have that 22 many, but -- 23 MR. TISI: I'll take a copy. Thank 24 you. 25 MR. ROTMAN: Thank you.</p>	<p style="text-align: right;">Page 29</p> <p>1 textbook. I believe I got -- I found this image 2 off of the internet. But I do have the fourth 3 and fifth editions of the Kurman Blaustein's 4 textbook, and I've marked any relevant pages that 5 I reviewed a couple of days ago. 6 MS. AHERN: If you -- 7 MR. ROTMAN: One second. 8 MS. AHERN: It might be easier if you 9 just hand me those and let me take a look. 10 MR. ROTMAN: In addition, there's the 11 boxes in the room that are the documents that 12 were sent up by counsel from Ashcraft & Gerel. 13 MS. AHERN: Thank you. 14 BY MS. AHERN: 15 Q. All right, Doctor. So let's take these 16 in order, I guess. Let's look at your -- 17 MR. ROTMAN: She also has a copy of her 18 report. 19 MS. AHERN: Okay. We'll mark your 20 updated CV as Exhibit No. 2. 21 (Curriculum vitae of Sarah E. 22 Kane, M.D. marked Exhibit 2.) 23 BY MS. AHERN: 24 Q. Do you need a copy in front of you? 25 A. Sure.</p>

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<p style="text-align: right;">Page 30</p> <p>1 Q. Okay.</p> <p>2 MS. AHERN: I don't know if anyone else</p> <p>3 needs a copy.</p> <p>4 BY MS. AHERN:</p> <p>5 Q. Doctor, Exhibit 2, this is a copy of</p> <p>6 your current curriculum vitae?</p> <p>7 A. Yes. January 2019, yes, this is the</p> <p>8 current.</p> <p>9 Q. And can you tell me what has been</p> <p>10 updated since you submitted your report</p> <p>11 November 15th of 2018?</p> <p>12 A. I believe the only change is that I am</p> <p>13 now director of cytopathology at North Shore</p> <p>14 Medical Center, which includes Salem Hospital and</p> <p>15 Union Hospital, which is in Lynn, Massachusetts.</p> <p>16 Q. Are there any additional publications</p> <p>17 that you have included on your updated resume --</p> <p>18 or, sorry, updated CV?</p> <p>19 A. I don't believe so.</p> <p>20 Q. The only change is that your position</p> <p>21 has changed to director?</p> <p>22 A. Yes, of cytopathology.</p> <p>23 Q. Okay. And you've also brought with you</p> <p>24 invoices --</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 32</p> <p>1 June 16th, which is the last date. So it would</p> <p>2 have been after June 16th, 2017.</p> <p>3 Q. I'm sorry. Do you remember when you</p> <p>4 were retained by the plaintiffs to be an expert</p> <p>5 in this litigation?</p> <p>6 A. I believe I was contacted by Mr. Rotman</p> <p>7 in early May of 2017.</p> <p>8 Q. Okay. Do you know how Mr. Rotman found</p> <p>9 your name?</p> <p>10 A. I believe he was referred by a</p> <p>11 colleague.</p> <p>12 Q. Do you remember what colleague that is?</p> <p>13 A. Dr. Paul Michaels.</p> <p>14 Q. And is Dr. Michaels a pathologist?</p> <p>15 A. Yes.</p> <p>16 Q. Where does Dr. Michaels work?</p> <p>17 A. I actually don't know the name of his</p> <p>18 group, but he is in Austin, Texas now.</p> <p>19 Q. Where was he in 2017?</p> <p>20 A. Austin, Texas, I believe.</p> <p>21 Q. Okay. Is he a gynecologic pathologist?</p> <p>22 A. No.</p> <p>23 Q. What type of pathologist is he?</p> <p>24 A. He has a cytopathology fellowship, in</p> <p>25 addition to anatomic and clinical board</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. -- for your time spent on talc?</p> <p>2 A. I handed them to her. Yes.</p> <p>3 MR. ROTMAN: What we handed, I think,</p> <p>4 is multiple copies, so you can hand one back, I</p> <p>5 suppose.</p> <p>6 MS. AHERN: We'll mark as Exhibit 3 to</p> <p>7 your deposition an invoice for rendered services.</p> <p>8 (Invoice from Sarah Kane, M.D.,</p> <p>9 for services 5/19 through 7/14 marked</p> <p>10 Exhibit 3.)</p> <p>11 MS. AHERN: I can't see a date, but it</p> <p>12 looks like it covers -- well, let's just have you</p> <p>13 look at it.</p> <p>14 BY MS. AHERN:</p> <p>15 Q. Can you tell me the date range covered</p> <p>16 by that invoice?</p> <p>17 MR. ROTMAN: Copy for me?</p> <p>18 A. Yes. It looks like it is from May 19th</p> <p>19 to June 16th. That would be -- if this is the</p> <p>20 first invoice, I believe, that would be of 2017,</p> <p>21 year 2017.</p> <p>22 Q. Okay. And, Doctor, was this May 19,</p> <p>23 2017 -- how long after you were retained did you</p> <p>24 submit this invoice?</p> <p>25 A. I wouldn't have sent it until after</p>	<p style="text-align: right;">Page 33</p> <p>1 certification.</p> <p>2 Q. And how do you know Dr. Michaels?</p> <p>3 A. We were residents and fellows together.</p> <p>4 Q. Were you -- fellows where? Mass</p> <p>5 General?</p> <p>6 A. At Massachusetts General, yes.</p> <p>7 Q. Was he in the gynecologic pathology</p> <p>8 fellowship with you or a different fellowship?</p> <p>9 A. So my fellowship was kind of</p> <p>10 interesting. I was, unfortunately, one of the</p> <p>11 last groups where a combined anatomic and</p> <p>12 clinical pathology residency was five years. I</p> <p>13 think the next year after I began residency they</p> <p>14 dropped it to four years.</p> <p>15 So my surgical pathology and cytopathology,</p> <p>16 it was a two-year fellowship. The gyn path and</p> <p>17 the cytopathology, it was over a two-year period.</p> <p>18 And the weeks of gynecologic pathology were mixed</p> <p>19 with weeks of cytopathology, so they spread out</p> <p>20 the cytopathology fellowship over two years.</p> <p>21 Paul was a cytopathology fellow the first</p> <p>22 year of my fellowship, so we did all four years</p> <p>23 of anatomic and clinical pathology and then the</p> <p>24 first year of fellowship at the same time.</p> <p>25 Q. Okay. And looking back at Exhibit 3,</p>

<p style="text-align: right;">Page 34</p> <p>1 this invoice from May 19, 2017, to July 14 of 2 2017, the first entry looks like it's -- it 3 covers a period of May 19th through July 14th, 4 "Communication with firm regarding talc 5 litigation case, one hour"; is that correct? 6 A. Yes. Sorry. Thank you for correcting 7 me. I saw the last line, 6/16, and figured that 8 was the last day that this covered. But you're 9 correct, it's -- July 14th would have been the 10 last date that this invoice covered. 11 Yes, June 16th I met with Mr. Rotman, 12 Dr. Thompson, and Mr. Soileau -- I don't know how 13 to pronounce his last name. 14 Q. Are they all -- they're all attorneys; 15 correct? 16 A. Correct. 17 Q. Okay. What firm? 18 A. I know Mr. Rotman is with Hausfeld. 19 Dr. Thompson is with Allen Beasley. I don't know 20 for sure where Mr. Soileau is from. 21 Q. You said Mr. Thompson is with Beasley 22 Allen. 23 A. I believe so. I don't remember for 24 certain. 25 Q. And at least during --</p>	<p style="text-align: right;">Page 36</p> <p>1 So those hours overlap a little bit. I 2 mean, I kept track of particular hours so that I 3 could bill accurately, but those two things -- 4 certainly, generating the medical expert report 5 would also include review of medical literature. 6 Q. Okay. So you started on your -- on the 7 draft of your expert report in this case back in 8 May of 2017; is that correct? 9 A. Late May, yes. 10 Q. And did you -- do you remember when you 11 started your review of the medical literature? 12 Would it have been May 20th, as reflected in this 13 invoice, Exhibit 3? 14 A. Yes, I believe so. 15 Q. You also have on here that you spent 16 some time researching electron microscopy 17 experts. 18 A. Yes. 19 Q. Was that at the request of the 20 plaintiffs' counsel? 21 A. Plaintiffs' counsel was looking for 22 additional people because there are very few 23 electron microscopy units in the country and very 24 few expert electron microscopists. 25 I can't remember if they asked me to or I</p>
<p style="text-align: right;">Page 35</p> <p>1 MR. ROTMAN: It's Ms. Thompson. 2 MS. AHERN: Ms. Thompson. 3 MR. ROTMAN: Or Dr. Thompson. 4 THE WITNESS: Doctor. She's a -- she's 5 a doctor, as well as an attorney. 6 Q. And for this first invoice, you billed 7 \$26,666.67; correct? 8 A. Yes. 9 Q. And you spent a total of 53 hours and 10 20 minutes working on talc-related issues? 11 A. Yes. 12 Q. Seventeen hours and five minutes of 13 that was reviewing the medical literature, expert 14 reports, and testimony; is that correct? 15 A. So this was my first time ever 16 recording any sort of invoice for medical expert 17 witness work, so the review of medical 18 literature, expert reports, and testimony, 19 probably some of that will also be included in 20 the generating of medical expert report, because 21 while I was -- I basically began -- you can see 22 from the dates I pretty much started drafting, 23 taking notes in a draft, around May 28th, which 24 was soon after I did my initial medical 25 literature searches.</p>	<p style="text-align: right;">Page 37</p> <p>1 offered to. It could have been the latter. But 2 I was aware that they were looking for additional 3 people to potentially use electron microscopy. 4 Q. Do you know how plaintiffs intended to 5 use the electron microscopy experts? 6 MR. ROTMAN: Objection. That's going 7 into areas that you're not entitled to, so she's 8 not going to answer that. 9 BY MS. AHERN: 10 Q. Doctor, what sort of electron 11 microscopists were you looking for at the 12 plaintiffs' request? 13 MR. ROTMAN: Same objection. 14 MS. AHERN: I'm not asking her about 15 communications that she had with counsel; I'm 16 asking her what sort of work -- 17 MR. ROTMAN: Your question -- 18 MS. AHERN: -- she did -- 19 MR. ROTMAN: Your question -- 20 MS. AHERN: -- that she was paid for by 21 the plaintiffs' counsel and that's reflected on 22 the invoice that you've submitted here today. 23 MR. ROTMAN: You are asking her what 24 she was doing at plaintiffs' counsel's request. 25 That's unrelated to her --</p>

<p style="text-align: right;">Page 38</p> <p>1 MS. AHERN: You're --</p> <p>2 MR. ROTMAN: -- opinions.</p> <p>3 MS. AHERN: -- instructing her not to</p> <p>4 answer the question of, "Doctor, what sort of</p> <p>5 electron microscopists were you looking for at</p> <p>6 plaintiffs' request?"</p> <p>7 MR. ROTMAN: Yes. I'm objecting to</p> <p>8 that.</p> <p>9 MR. KLATT: That's not a communication.</p> <p>10 MS. AHERN: That's not a communication.</p> <p>11 That is what did she do and what was she looking</p> <p>12 for.</p> <p>13 MR. TISI: It's consulting.</p> <p>14 MS. AHERN: She's sitting here today as</p> <p>15 a testifying expert.</p> <p>16 MR. ROTMAN: Understood. She's not</p> <p>17 going to answer that.</p> <p>18 BY MS. AHERN:</p> <p>19 Q. Doctor, did you make any</p> <p>20 recommendations regarding electron microscopists?</p> <p>21 A. No, ultimately, I did not give them any</p> <p>22 names.</p> <p>23 Q. What electron microscopists were you</p> <p>24 looking at when you were conducting your</p> <p>25 research?</p>	<p style="text-align: right;">Page 40</p> <p>1 P-E-T-U-R.</p> <p>2 Q. N-I-E-, Nielsen?</p> <p>3 A. I believe so.</p> <p>4 Q. -S-S-O-N?</p> <p>5 A. No, -L-S-E-N.</p> <p>6 Q. Did you speak to Dr. Nielsen about</p> <p>7 potentially working on the talc litigation?</p> <p>8 A. I believe I e-mailed him.</p> <p>9 Q. Do you remember when that occurred?</p> <p>10 A. It was probably -- I don't remember</p> <p>11 exactly, but I would imagine it was between 5/22</p> <p>12 and 6/1 of 2017.</p> <p>13 Q. And was he interested in doing any talc</p> <p>14 work?</p> <p>15 A. He was not interested in doing medical</p> <p>16 expert witness or consulting work.</p> <p>17 Q. Did you e-mail anybody else, any other</p> <p>18 electron microscopists?</p> <p>19 MR. ROTMAN: So you keep on asking her</p> <p>20 about the consulting work that she was doing that</p> <p>21 had nothing to do with her opinions in this case,</p> <p>22 which is why we're here today. We're not here</p> <p>23 today for you to take the deposition of her</p> <p>24 consulting work at that stage on this issue, so</p> <p>25 that whole area is off limits and I'm instructing</p>
<p style="text-align: right;">Page 39</p> <p>1 MR. ROTMAN: Again, this is her work</p> <p>2 on -- as a consultant not relating to her</p> <p>3 opinions in this case --</p> <p>4 Q. Doctor, do you --</p> <p>5 MR. ROTMAN: -- so you're not entitled</p> <p>6 to this information.</p> <p>7 MS. AHERN: You're instructing her not</p> <p>8 to answer.</p> <p>9 MR. ROTMAN: Yes.</p> <p>10 MS. AHERN: Then instruct her not to</p> <p>11 answer.</p> <p>12 MR. ROTMAN: I'm instructing you not to</p> <p>13 answer.</p> <p>14 THE WITNESS: Okay.</p> <p>15 BY MS. AHERN:</p> <p>16 Q. Doctor, do you know any electron</p> <p>17 microscopists?</p> <p>18 A. Yes.</p> <p>19 Q. Who?</p> <p>20 A. I know Dr. Gunnlaugur Nielsen at</p> <p>21 Massachusetts General Hospital.</p> <p>22 Q. How do you spell Gunnlaugur's name?</p> <p>23 A. G-U-N-N -- I believe there are two</p> <p>24 Ns -- L-A-U-G-H-E-R [sic], Nielsen. That's with</p> <p>25 an S-E-N. But he goes by Petur, which is</p>	<p style="text-align: right;">Page 41</p> <p>1 her not to answer. If you want to continue</p> <p>2 asking those questions, I'm going to continue to</p> <p>3 object on the same basis.</p> <p>4 Q. Doctor, did you contact any electron</p> <p>5 microscopists who agreed to work on the talc</p> <p>6 litigation?</p> <p>7 MR. ROTMAN: Objection.</p> <p>8 Instruct you not to answer for the</p> <p>9 reasons previously provided.</p> <p>10 Q. Doctor, do you know a Dr. Champion?</p> <p>11 A. I do not.</p> <p>12 Q. Do you know a Dr. John Godleski?</p> <p>13 A. I know the name. I do not know him</p> <p>14 personally.</p> <p>15 Q. Do you know Bill Welch?</p> <p>16 A. I know the name. I do not know him</p> <p>17 personally.</p> <p>18 Q. Okay.</p> <p>19 (Invoice from Sarah Kane, M.D.,</p> <p>20 for services 7/28 through 9/12 marked</p> <p>21 Exhibit 4.)</p> <p>22 BY MS. AHERN:</p> <p>23 Q. Doctor, I'm handing you what's been</p> <p>24 marked as Exhibit 4 to your deposition.</p> <p>25 Can you tell me what that is?</p>

Sarah F. Kane, M.D.

<p style="text-align: right;">Page 42</p> <p>1 A. This is probably the second invoice. 2 Again, I don't believe I had it numbered on the 3 actual invoice, but this looks like it would be 4 the second invoice. 5 Q. And what period of time does Exhibit 4 6 cover? 7 A. This covers July 28th to September 12. 8 Q. Is this 2017? 9 A. Yes. 10 Q. And you spent an additional 37 hours 11 and 40 minutes reviewing literature and 12 generating your expert report; is that correct? 13 A. Right. And you'll see I actually 14 combined everything, because it got too 15 complicated to separate them out. And generating 16 the medical expert report was sort of this 17 organic part of reviewing the literature. 18 Q. And the total bill was for \$19,666.67; 19 correct? 20 A. Yes. 21 Q. Okay. Was all your time on Exhibit 4 22 spent working on your MDL report? 23 A. I'm sorry. This invoice? 24 Q. Yes, ma'am. Was the time spent on 25 Exhibits 3 and 4, these first two invoices, was</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. Who's been your primary contact? 2 A. Mr. Rotman. 3 Q. Okay. And a total for that bill was 4 \$13,835; is that correct? 5 A. Yes. 6 (Invoice from Sarah Kane, M.D., 7 for services 2/23/18 through 8/3/18 marked 8 Exhibit 6.) 9 BY MS. AHERN: 10 Q. I'm handing you what's been marked as 11 Exhibit 6 to your deposition. 12 Can you tell me what that document is, 13 please? 14 A. So this -- I'm counting now -- looks 15 like this is the fourth invoice -- yes, the 16 fourth invoice that I sent them. 17 Q. And what period of time does this 18 Exhibit 6 cover? 19 A. It looks like February 23rd, 2018, 20 through August 7th, 2018. 21 Q. Okay. And Exhibit 6 reflects that you 22 spent an additional 16 hours and 55 minutes 23 reviewing literature and generating your medical 24 expert report; is that correct? 25 A. Yes.</p>
<p style="text-align: right;">Page 43</p> <p>1 this all in relation to your work on the talc 2 MDL? 3 A. Yes. I'm not involved in any other 4 talc litigation. 5 Q. Okay. 6 MS. AHERN: Okay. I'm marking 7 Exhibit 5 as -- oh, I'm marking, sorry, your 8 third invoice as Exhibit 5 to your deposition. 9 (Invoice from Sarah Kane, M.D., 10 for services 9/18/17 through 2/5/18 marked 11 Exhibit 5.) 12 BY MS. AHERN: 13 Q. This is a copy of an invoice submitted 14 by you; correct? 15 A. Yes. 16 Q. And what dates does it cover? 17 A. This covers September 18th, 2017, to 18 February 5th, 2018. 19 Q. You spent an additional 27 hours and 40 20 minutes working on your report; is that correct? 21 A. Yes. Well, 21 hours, 55 minutes 22 reviewing the literature and the medical expert 23 witness report, and then there were a few hours 24 communicating and meeting with the firm, which 25 would likely be Mr. Rotman.</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. And 3 hours and 30 minutes 2 communicating or meeting with the law firms 3 involved. 4 A. Correct. 5 Q. Okay. And the total for that invoice 6 was \$10,208; correct? 7 A. Correct. 8 Q. Okay. I'm handing you what's been 9 marked as Exhibit 7 to your deposition. 10 (Invoice from Sarah Kane, M.D., 11 for services 9/20/18 through 11/16/18 12 marked Exhibit 7.) 13 BY MS. AHERN: 14 Q. And this is another invoice prepared by 15 you? 16 A. Yes. 17 Q. And the period of time that is covered 18 appears to be September 20th, 2018, through 19 November 16th of 2018; is that right? 20 A. Yes. 21 Q. And you spent an additional 71 hours 22 and 5 minutes reviewing materials and generating 23 your expert report? 24 A. Yes. 25 Q. And about four-and-a-half hours</p>

<p style="text-align: right;">Page 46</p> <p>1 communicating with the law firms involved?</p> <p>2 A. That's correct.</p> <p>3 Q. For a total of \$37,791.67?</p> <p>4 A. Yes.</p> <p>5 Q. Doctor, do you have any -- this takes</p> <p>6 us through -- this last invoice, Exhibit 7, takes</p> <p>7 us through November of 2018.</p> <p>8 You've done additional work since November</p> <p>9 of 2018; correct?</p> <p>10 A. I have.</p> <p>11 Q. Do you know how much time you have yet</p> <p>12 to invoice or -- sorry, let me back up. Withdraw</p> <p>13 that.</p> <p>14 Have you sent another invoice to plaintiffs'</p> <p>15 counsel?</p> <p>16 A. I have not.</p> <p>17 Q. Okay. Do you have any idea how many</p> <p>18 hours you have yet to invoice?</p> <p>19 A. I have not added it up. I don't really</p> <p>20 have a ballpark. Maybe -- I would just be</p> <p>21 guessing. I haven't added it up, to be honest.</p> <p>22 Q. Do you know how much money you've made</p> <p>23 to date, totaling all of these together?</p> <p>24 MR. ROTMAN: Objection.</p> <p>25 Q. How much money -- how much money have</p>	<p style="text-align: right;">Page 48</p> <p>1 and produce it to one of the attorneys involved?</p> <p>2 A. Sure.</p> <p>3 Q. Thank you.</p> <p>4 MR. ROTMAN: She'll find it if it</p> <p>5 exists. She'll look for it.</p> <p>6 MS. AHERN: Clearly.</p> <p>7 MR. ROTMAN: She didn't testify that</p> <p>8 she produced a fee schedule; she said she</p> <p>9 believed she did.</p> <p>10 MS. AHERN: Understood. If she finds</p> <p>11 it --</p> <p>12 MR. ROTMAN: Yeah.</p> <p>13 MS. AHERN: -- she'll produce it to you</p> <p>14 and you'll produce it to us.</p> <p>15 MR. ROTMAN: Exactly.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. Doctor, how much -- I mean, how do you</p> <p>18 keep track of your time? Do you have a</p> <p>19 spreadsheet? Do you have some process where you</p> <p>20 log your hours?</p> <p>21 A. I keep a list, an electronic list.</p> <p>22 It's not an Excel, but it's just a list.</p> <p>23 Q. So is it just a Word document and you</p> <p>24 put your time entries in and multiply that by</p> <p>25 your hourly rate?</p>
<p style="text-align: right;">Page 47</p> <p>1 you made in fees associated with your talc work</p> <p>2 to date?</p> <p>3 A. I would need a calculator to add it all</p> <p>4 up, but this would be the full amount, all added</p> <p>5 together.</p> <p>6 Q. And, Doctor, you're charging \$500 an</p> <p>7 hour; correct?</p> <p>8 A. Yes.</p> <p>9 Q. Did you ask for a retainer when you</p> <p>10 were initially asked to get involved in the case?</p> <p>11 A. I did not.</p> <p>12 Q. Were you offered a retainer?</p> <p>13 A. It wasn't discussed.</p> <p>14 Q. Does the amount that you charge or your</p> <p>15 fee, does that change with the activity that</p> <p>16 you're performing?</p> <p>17 A. No. I think I had a fee schedule where</p> <p>18 trial might be on a per-day basis, but I don't</p> <p>19 remember what that is.</p> <p>20 Q. Did you actually submit a written fee</p> <p>21 schedule to the plaintiffs' counsel?</p> <p>22 A. I believe I did at some point.</p> <p>23 MR. ROTMAN: I don't know. I don't</p> <p>24 recall that.</p> <p>25 Q. Could you find a copy of that, please,</p>	<p style="text-align: right;">Page 49</p> <p>1 A. Basically.</p> <p>2 Q. And do you generate the invoices</p> <p>3 yourself?</p> <p>4 A. I do.</p> <p>5 Q. Is that through some sort of program or</p> <p>6 is this just a Word document that you created and</p> <p>7 you plug the information in?</p> <p>8 A. It's just a Word document.</p> <p>9 (Discussion off the record.)</p> <p>10 BY MS. AHERN:</p> <p>11 Q. So, Doctor, other than the folders that</p> <p>12 we've just gone through, is there anything</p> <p>13 related to your opinions in this case that you</p> <p>14 did not bring with you to the deposition today?</p> <p>15 MR. ROTMAN: Objection.</p> <p>16 Q. Start with that.</p> <p>17 MR. ROTMAN: Objection.</p> <p>18 A. I believe I brought all of the</p> <p>19 literature cited in the initial reports. I've</p> <p>20 tried to be complete, as you know, with listing</p> <p>21 everything that I've reviewed. It's possible</p> <p>22 there might have been some things that I reviewed</p> <p>23 that I forgot to put on a list, but I've tried to</p> <p>24 be as complete as possible.</p> <p>25 Q. How did you track your literature</p>

<p style="text-align: right;">Page 50</p> <p>1 reviews?</p> <p>2 A. So when I was writing the report,</p> <p>3 you'll notice the first reference list is a list</p> <p>4 of papers that I actually cited in the text of</p> <p>5 the report, and then I had -- any papers that I</p> <p>6 reviewed or other data that I reviewed, I kept in</p> <p>7 folders on my computer.</p> <p>8 Unfortunately, I had two hard drives</p> <p>9 malfunction while I was in the process of writing</p> <p>10 this report. Luckily, I backed up most of it, so</p> <p>11 it's possible a few things didn't get documented,</p> <p>12 ultimately, but I really tried my best to make it</p> <p>13 complete and accurate, and that's why you got</p> <p>14 another list yesterday.</p> <p>15 Q. Okay. And, I'm sorry, we forgot to</p> <p>16 mark some of these.</p> <p>17 And so can you tell me -- this is something</p> <p>18 you brought with you today?</p> <p>19 A. Yes.</p> <p>20 MR. TISI: Can I -- and he's defending</p> <p>21 the deposition; I just have a little more</p> <p>22 knowledge of the documents and how they -- at</p> <p>23 least I think I do.</p> <p>24 I think that in the boxes here are the</p> <p>25 references cited. The materials considered, I</p>	<p style="text-align: right;">Page 52</p> <p>1 MR. KLATT: Chris, let me just clarify.</p> <p>2 There's four blue cardboard TLS boxes --</p> <p>3 MR. TISI: Correct.</p> <p>4 MR. KLATT: -- that you're referring</p> <p>5 to?</p> <p>6 MR. TISI: Correct.</p> <p>7 MR. KLATT: And they have binders in</p> <p>8 them?</p> <p>9 MR. TISI: They have binders in them.</p> <p>10 And I haven't even looked at them because they</p> <p>11 were sent out from the Ashcraft office, but my</p> <p>12 understanding -- and you can crack them open at</p> <p>13 break -- but my understanding is there are copies</p> <p>14 of those. I don't know how many. So it's four</p> <p>15 boxes, but there are duplicates in there.</p> <p>16 But they are -- if I understand -- and</p> <p>17 I can correct them on a break -- if I understand</p> <p>18 them, they are copies of the references. We did</p> <p>19 not make copies -- or they did not make copies of</p> <p>20 the materials that were considered but not</p> <p>21 referenced in the reports.</p> <p>22 Do you follow what I'm saying?</p> <p>23 MR. KLATT: Yeah. What I want to</p> <p>24 clarify is the four boxes here have not been in</p> <p>25 Dr. Kane's possession, so there's no notations,</p>
<p style="text-align: right;">Page 51</p> <p>1 don't think we printed out. I don't think those</p> <p>2 are in the boxes. And so I don't want there to</p> <p>3 be any -- there are documents she reviewed that</p> <p>4 are not here that are not referenced, but were</p> <p>5 identified in that list.</p> <p>6 Does that make sense?</p> <p>7 MS. AHERN: Maybe. I'm going to go</p> <p>8 through the various reference lists with her --</p> <p>9 MR. TISI: Okay.</p> <p>10 MS. AHERN: -- and we can kind of</p> <p>11 clarify as we go.</p> <p>12 MR. TISI: Like, for example, I mean, I</p> <p>13 just -- I'm just using an example -- we</p> <p>14 supplemented with some Health Canada materials.</p> <p>15 I don't know if she brought those with her,</p> <p>16 because they were not in the original report.</p> <p>17 They weren't available at the time, so they would</p> <p>18 not be in the reference materials that are in the</p> <p>19 binders.</p> <p>20 I know you haven't cracked open the</p> <p>21 boxes, but I don't want there to be any</p> <p>22 misimpression. So in terms of what they are, you</p> <p>23 can certainly ask her, but she may not know what</p> <p>24 is in the boxes, because we printed them out for</p> <p>25 her. Do you know what I'm saying?</p>	<p style="text-align: right;">Page 53</p> <p>1 highlighting, stickies --</p> <p>2 MR. TISI: Oh, no.</p> <p>3 MR. KLATT: -- that she -- that</p> <p>4 Dr. Kane herself would have put on what's in the</p> <p>5 boxes --</p> <p>6 MR. TISI: No. Those were print- --</p> <p>7 MR. KLATT: -- is that correct?</p> <p>8 MR. TISI: Correct. Those were printed</p> <p>9 out by the plaintiffs' steering committee.</p> <p>10 Basically, we took her reference list and printed</p> <p>11 them out for you all. There's no -- there are no</p> <p>12 notes from her or anything like that.</p> <p>13 What I don't think we printed out for</p> <p>14 you would be the extensive documents that she</p> <p>15 reviewed, including the supplemental materials</p> <p>16 that were identified, and then put them -- we can</p> <p>17 provide those in a -- you know, on a thumb drive</p> <p>18 if you want to. It's just in these depositions</p> <p>19 we've had so far, half the time the boxes aren't</p> <p>20 even opened, and we didn't want to just create</p> <p>21 paper for the purpose of creating paper. But if</p> <p>22 you want, we can pull those for you and put them</p> <p>23 in a Dropbox or whatever.</p> <p>24 I don't want to waste your time,</p> <p>25 because I do want there to be -- because she</p>

Sarah E. Kane, M.D.

<p style="text-align: right;">Page 54</p> <p>1 doesn't necessarily know what was printed out for 2 her. 3 MS. AHERN: Understood. So let's -- 4 MR. TISI: I'm sorry if I -- 5 MS. AHERN: That's okay. 6 MR. TISI: -- took up time. 7 (Excerpt from Blaustein's Second 8 marked Exhibit 8.) 9 BY MS. AHERN: 10 Q. Doctor, I'm handing you what's been 11 marked as Exhibit 8 to your deposition. 12 A. Yes. 13 Q. Is this something that you brought with 14 you today in response to the Notice of 15 Deposition? 16 A. It's something I brought because I 17 reviewed it a couple days ago. It probably falls 18 within the deposition. I know you wanted to see 19 everything that I reviewed. 20 Q. So, first of all, tell me what this is. 21 What is Exhibit 8? 22 A. This is a page from Blaustein's second 23 edition of the Pathology of the Female Genital 24 Tract. 25 Q. Do you know what page it is?</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. And, Doctor, the additional materials 2 to -- of Dr. Sarah Kane that were provided to us 3 yesterday, you list "Kurman defense report" from 4 a case by the name of Ristesund. 5 Did you not receive that? 6 A. I asked for -- yeah, I did receive 7 that. 8 Q. You received it? 9 MR. ROTMAN: What she -- what she was 10 saying is she -- 11 MS. AHERN: Wait. I'm asking her the 12 question. 13 Q. Did you receive the report, the Kurman 14 defense report, from a case by the name of 15 Ristesund? 16 A. Yes. I had requested a defense report 17 written by Kurman, if they had anything, and that 18 is what I received. 19 Q. Okay. I thought just a minute ago you 20 said you had not received one because it wasn't 21 available to you. 22 A. I'm talking about the MDL, the curr- -- 23 Q. Ah. 24 A. -- the current defense expert witness 25 reports.</p>
<p style="text-align: right;">Page 55</p> <p>1 A. Unfortunately, it is cut off. This -- 2 I don't have this textbook. I found this, I 3 think, on Google Books, actually. 4 Q. And so why are you bringing it today 5 again? 6 A. Because I reviewed it. 7 Q. Okay. And why did you review this? 8 A. Well, I recently became aware that 9 Dr. Kurman is a medical expert witness for the 10 defense, so I was more curious. I actually asked 11 the plaintiffs' attorneys for a report -- any 12 report that Dr. Kurman had done, because I was 13 trying to understand his -- what his viewpoint 14 might be. I don't have his defense report 15 because they're not available to us yet, but I 16 was trying to get a sense for what defense 17 medical experts -- their viewpoints. 18 And so I did a search for, basically, "talc" 19 and "Kurman" and I found this (indicating). And 20 then I have two other editions, so I looked 21 through my other editions for any references to 22 talc. Because Kurman edited the fourth and fifth 23 edition. I do not believe he edited the second 24 edition, which is -- this one page is from 25 (indicating).</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. Okay. 2 A. Yeah. 3 Q. Thank you for the clarification. 4 So you have seen at least one defense report 5 that was written by Dr. Bob Kurman; right? 6 A. Yes. 7 Q. And did you -- do you know Dr. Robert 8 Kurman, either personally or by reputation? 9 A. By reputation and I've gone to dinner 10 with him before, but I don't know him well. 11 Q. And what do you know about Dr. Kurman? 12 A. So he is a well-known gynecologic 13 pathologist out of -- he was out of Johns 14 Hopkins. I believe he recently retired. 15 But he certainly edited one of the main 16 gynecologic pathology textbooks and was -- you 17 know, published quite a bit in gynecologic 18 pathology, so his name is well known in our 19 community. 20 Q. And you've actually cited to a number 21 of his papers in your report; correct? 22 A. Yes, I'm sure I have. I know at least 23 one or two. 24 Q. And Dr. Kurman was a Robert Scully 25 fellow, as well, wasn't he?</p>

<p style="text-align: right;">Page 58</p> <p>1 A. I actually don't remember if he trained 2 under Scully. It's possible. I don't remember 3 whether or not he did. 4 Q. Okay. This Exhibit 8 that you brought 5 with you today, are you bringing it here because 6 it mentions granulomatous endometritis caused by 7 foreign bodies? 8 A. It says, "Talc may be introduced into 9 the endometrial cavity by instruments 10 contaminated with talcum powder or by gloves 11 during a pelvic examination. Patients may be 12 asymptomatic or may present with menorrhagia. 13 Microscopically, the extent of the granulomatous 14 inflammatory reaction depends on the quantity of 15 the talc inoculated. The infiltrate is 16 characterized by histiocytes and foreign-body 17 multinucleated giant cells surrounded -- 18 surrounding the talc crystals, along with 19 lymphocytes and plasma cells. The crystals 20 appear as refractile, birefringent, needle-like, 21 or fan-shaped splinters in polarizing light." 22 Q. Are you familiar with the type of 23 reactions -- tissue reactions that are elicited 24 by talc in tissue? 25 A. I know -- I'm aware that you can get</p>	<p style="text-align: right;">Page 60</p> <p>1 A. I'm not really sure what you mean by 2 "types." You mean foreign body versus infectious 3 versus -- 4 Q. Yes. 5 A. Those would be the top of the list. 6 Q. And are there subtypes of granulomatous 7 inflammation within those categories? 8 A. Well, you can have multinucleated giant 9 cells that aren't part of a granuloma. 10 You can see -- another common situation 11 where you'll see granulomas is in Crohn's 12 disease. That's granulomatous inflammation in 13 the colon due to inflammatory bowel disease. 14 And I think -- yeah. So foreign body and 15 infection are -- and certain diseases that may 16 cause granulomatous -- that's sort of the 17 hallmark of that type of disease, sarcoidosis. 18 Q. Have you ever -- the Figure 12.6 in 19 Exhibit 8 actually doesn't have anything to do 20 with granulomatous endometritis, does it? 21 A. No. That figure is of a type of 22 finding you can see in the endometrium that's not 23 a granulomatous reaction. 24 Q. And how did Exhibit 8, if it does, 25 inform your opinions in this case?</p>
<p style="text-align: right;">Page 59</p> <p>1 granulomatous -- granulomatous inflammation, like 2 here, and you can have acute inflammation, for 3 example, in pleurodesis and chronic inflammation, 4 like lymphocytes and plasma cells. 5 Q. Are you an expert in granulomatous 6 inflammation? 7 A. Well, I certainly am familiar with 8 the -- with diagnosis of granulomatous 9 inflammation. I see it quite commonly. 10 Q. Under what circumstances do you 11 commonly see granulomatous inflammation? 12 A. You see it often in -- the most common 13 situation would be foreign-body giant cell. That 14 could be due to foreign bodies or it could be due 15 to -- a common situation we might see them is 16 what's called an epidermal inclusion cyst in the 17 skin, and you actually can get a granulomatous 18 response to keratin that has -- if it's ruptured 19 and gone into the dermis, you can see that. 20 Infections is another one. In tuberculosis, 21 you can see granulomatous inflammation. Fungal 22 infections, you can see granulomatous 23 inflammation. 24 Q. How many different types of 25 granulomatous reactions are there?</p>	<p style="text-align: right;">Page 61</p> <p>1 A. Well, it was just a piece of 2 information I found, again because I was curious 3 mostly about what Kurman's opinion might be on 4 this litigation. So... 5 Q. Does -- do you know what -- did this 6 come from a particular chapter in Blaustein's 7 second edition? 8 A. This, I don't -- I have no more 9 information on this particular one. Um -- 10 Q. Do you know who authored the chapter? 11 MR. ROTMAN: Excuse me. I think she 12 was in the middle of an answer. 13 Q. I didn't mean to cut you off. Please 14 go ahead. 15 A. Again, I don't have any more 16 information. I brought it because I saw it. 17 Q. Okay. So you don't know who authored 18 the chapter that contains this information in 19 Exhibit 8? 20 A. Not for this edition, I do not. 21 Q. And are you -- do you -- did you say 22 earlier you weren't sure if Dr. Kurman edited 23 this particular version of Blaustein's Pathology? 24 A. I don't believe he did. I know he 25 edited the fourth and fifth, but I don't believe</p>

<p style="text-align: right;">Page 62</p> <p>1 he did the second.</p> <p>2 Q. Does the information in Exhibit 8</p> <p>3 inform your decisions regarding talc and</p> <p>4 causation with regard to ovarian cancer?</p> <p>5 MR. ROTMAN: Objection.</p> <p>6 A. It's another piece of evidence. It</p> <p>7 mentions granulomatous inflammation due to talc</p> <p>8 in the endometrium.</p> <p>9 Q. And what does that have to do with</p> <p>10 ovarian cancer?</p> <p>11 A. Well, one of the plausible biologic</p> <p>12 mechanisms for talc causing ovarian cancer is</p> <p>13 that it elicits a chronic inflammatory reaction.</p> <p>14 Q. And there are different types of</p> <p>15 chronic inflammatory reactions, aren't there?</p> <p>16 A. Yes, there are.</p> <p>17 Q. Is a foreign-body reaction the same as</p> <p>18 the type of inflammation seen, for instance, in</p> <p>19 ulcerative colitis? If you know.</p> <p>20 A. No, I'm just rereading the question.</p> <p>21 Ulcerative colitis, you don't typically see</p> <p>22 foreign-body reaction.</p> <p>23 Q. Ulcerative colitis is one of the</p> <p>24 conditions that has been associated with the</p> <p>25 development of cancer; correct?</p>	<p style="text-align: right;">Page 64</p> <p>1 going to --</p> <p>2 MS. AHERN: One second, please.</p> <p>3 Q. You can see inflammatory conditions</p> <p>4 that are not in any way linked to the development</p> <p>5 of cancer; correct?</p> <p>6 A. So not all chronic inflammation is</p> <p>7 going to lead to cancer, but chronic inflammation</p> <p>8 is a well-established cause of different types of</p> <p>9 cancer.</p> <p>10 MR. ROTMAN: I'd like to take a break.</p> <p>11 We've been going a little over an hour.</p> <p>12 MS. AHERN: Okay.</p> <p>13 THE VIDEOGRAPHER: Here ends Media 1.</p> <p>14 Off the record, 10:21 a.m.</p> <p>15 (A recess was taken.)</p> <p>16 THE VIDEOGRAPHER: Here begins Media</p> <p>17 No. 2 in today's deposition of Sarah Kane, M.D.</p> <p>18 Back on the record, 10:37 a.m.</p> <p>19 BY MS. AHERN:</p> <p>20 Q. All right. Dr. Kane, we were -- we</p> <p>21 left off, we were talking about chronic</p> <p>22 inflammation and cancer.</p> <p>23 Do you remember that?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. Can you identify for me the</p>
<p style="text-align: right;">Page 63</p> <p>1 A. Those with ulcerative colitis have an</p> <p>2 increased risk of colon cancer, yes.</p> <p>3 Q. Do you know of any particular cancers</p> <p>4 that have been linked to foreign-body responses?</p> <p>5 A. Well, foreign-body responses -- for</p> <p>6 example, asbestos is known to cause an</p> <p>7 inflammatory response and asbestos is known to</p> <p>8 cause mesothelioma and lung cancer, and the IARC</p> <p>9 states that it causes ovarian cancer.</p> <p>10 Q. And how is the response to asbestos</p> <p>11 different from the response that's been</p> <p>12 documented with talc in terms of tissue reaction?</p> <p>13 A. So you can see a granulomatous reaction</p> <p>14 to talc. You can see an acute reaction to talc</p> <p>15 in pleurodesis patients.</p> <p>16 This page here mentions plasma cells and</p> <p>17 lymphocytes, which you do see in Crohn's disease.</p> <p>18 Q. You see plasma cells and lymphocytes in</p> <p>19 a number of different inflammatory conditions;</p> <p>20 correct?</p> <p>21 MR. ROTMAN: You can answer.</p> <p>22 A. Yes, you can see lymphocytes and plasma</p> <p>23 cells in inflammatory conditions.</p> <p>24 Q. And you can see inflammatory con- --</p> <p>25 MR. ROTMAN: Object -- object -- I was</p>	<p style="text-align: right;">Page 65</p> <p>1 types of ovarian cancer that have been associated</p> <p>2 with chronic inflammation?</p> <p>3 A. So we know that endometriosis, as an</p> <p>4 example, causes an inflammatory response. The</p> <p>5 types of ovarian cancer that are associated with</p> <p>6 endometriosis are clear cell carcinoma and</p> <p>7 endometrioid carcinoma.</p> <p>8 Q. Are there other forms of ovarian cancer</p> <p>9 that are associated in the literature with</p> <p>10 chronic inflammation?</p> <p>11 A. So we do see chronic inflammation</p> <p>12 within other types of ovarian cancer, so</p> <p>13 high-grade invasive serous, low-grade serous</p> <p>14 carcinoma, you do see chronic inflammation within</p> <p>15 those tumors.</p> <p>16 Q. Let me be more precise, because it's</p> <p>17 sort of a chicken and the egg kind of thing.</p> <p>18 I'm asking what sort of inflammatory</p> <p>19 conditions have been associated with the</p> <p>20 development or the cause of ovarian cancers?</p> <p>21 A. Yeah. So the mechanisms of a lot of</p> <p>22 ovarian cancer have been somewhat elusive.</p> <p>23 Unfortunately, it's a rare disease. It's hard to</p> <p>24 study. It's difficult to have sort of a large</p> <p>25 enough cohort to really get good data on ovarian</p>

<p style="text-align: right;">Page 66</p> <p>1 cancer, and so we don't really know all of the 2 mechanisms of the initiation of ovarian cancer. 3 But we know that chronic inflammation, we 4 see it in ovarian tumors. We know that -- and 5 putting it in a talc perspective, we know that 6 talc can cause chronic inflammation and so -- and 7 we know that chronic inflammation causes other 8 types of cancer. 9 Q. So is that -- can you name any other 10 types of ovarian cancers that have been 11 associated in the literature with chronic 12 inflammation in terms of a specific etiology for 13 that cancer? 14 A. So, again, I would say I don't know if 15 we can say for certain what the specific etiology 16 is for all types of surface epithelial cancer, 17 but we do know that, again, clear cell has been 18 associated with endometriosis, which causes 19 chronic inflammation, and we see chronic 20 inflammation in tumors. But the mechanisms for 21 these types of tumors have not been completely 22 mechan- -- elucidated. 23 Q. So do you not know of any other 24 specific ovarian tumors that have been associated 25 in the literature causally with chronic</p>	<p style="text-align: right;">Page 68</p> <p>1 inflammation, yes. 2 Q. And you would agree that many, if not 3 most, cancers are somewhat proinflammatory. 4 A. I think tumors can be -- can be 5 proinflammatory, yes. 6 Q. So the tumor itself can invoke an 7 inflammatory response during its development; 8 correct? 9 A. Some tumors will. 10 Q. And often the tumors will hijack 11 portions of the immune system to help them to 12 grow and metastasize; correct? 13 A. I'm not sure exactly what you mean by 14 "hijack," but there are mechanisms to -- or 15 literature to suggest that. 16 Q. So just looking at a high-grade serous 17 carcinoma and seeing inflammation doesn't tell 18 you anything about whether that inflammation 19 caused the tumor or whether it was caused by the 20 tumor; is that correct? 21 A. So, again, the mechanisms are not that 22 clear, so we don't know for sure. But is all 23 chronic inflammation seen in a tumor the cause of 24 the tumor? I don't know if we know the answer, 25 but, you know, it's definitely an associated</p>
<p style="text-align: right;">Page 67</p> <p>1 inflammation? 2 A. Again, I don't believe that the 3 mechanisms of all of these tumors have been 4 elucidated completely. 5 Q. And I do understand your answer, but I 6 just want to know if there are -- if you're aware 7 of literature connecting causally chronic 8 inflammation with other types of ovarian cancer 9 other than the two that you've mentioned, 10 endometrioid and clear cell carcinoma. 11 A. Well, again, I mentioned that in serous 12 tumors, we do see chronic inflammation in those 13 tumors. 14 And with smoking and mucinous ovarian 15 cancers, you know, it's been -- there's some 16 literature that suggests, you know, smoking is 17 associated with mucinous and those -- that can 18 cause inflammatory reactions. 19 But, again, this is all -- it's not entirely 20 clear what the etiology of some of these tumors 21 are. 22 Q. You mentioned that in high-grade serous 23 carcinoma, you see associated inflammation; 24 correct? 25 A. You can see associated chronic</p>	<p style="text-align: right;">Page 69</p> <p>1 pattern that we see with ovarian tumors. 2 Q. So my question is a little different, 3 if I can go back and find it. And it's missing. 4 My question is: As a pathologist looking at 5 slides from a particular patient who has ovarian 6 cancer -- 7 A. Mm-hmm. 8 Q. -- just the observation that there is 9 inflammatory cells associated with that tumor 10 doesn't tell you anything, as a pathologist, in 11 terms of whether that inflammation caused the 12 tumor or if the tumor caused the inflammation. 13 A. Well, I think it depends on the 14 situation. You know, again, for ovarian tumors, 15 if we have a clear cell carcinoma, we could, you 16 know, deduce, especially if you see associated 17 endometriosis, that that is the likely cause, 18 and, again, depending on the patient and the 19 patient's risk factors. 20 But, yeah, if you're looking just at one 21 slide without any other information, it would be 22 difficult to say. 23 Q. Well, you would never just be looking 24 at one slide, would you? You'd be looking at all 25 of the slides that were available for a</p>

<p style="text-align: right;">Page 70</p> <p>1 particular patient, which would include</p> <p>2 diagnostic tissue or tumor tissue, as well as</p> <p>3 normal, nontumor tissue; correct?</p> <p>4 A. Right.</p> <p>5 Q. Okay. So you would never be in a</p> <p>6 situation where you're just looking at a single</p> <p>7 slide and making a determination, unless it's</p> <p>8 maybe cytology or a biopsy; correct?</p> <p>9 A. I'm sorry. I'm just looking at the --</p> <p>10 Q. Sure.</p> <p>11 A. I'm not sure what the -- the first</p> <p>12 question came out kind of funny.</p> <p>13 Q. What I was saying is there would never</p> <p>14 be a situation where you're only looking at a</p> <p>15 single slide to make a diagnostic determination</p> <p>16 unless it was from a biopsy sample or a cytology.</p> <p>17 A. That's what I was going to kind of</p> <p>18 rewind and clarify, that sometimes there is only</p> <p>19 one slide. So --</p> <p>20 Q. Is that an accurate statement?</p> <p>21 MR. ROTMAN: Let her finish the answer.</p> <p>22 I think she was saying "so" and then you asked</p> <p>23 another question.</p> <p>24 A. So in a larger specimen type, it's</p> <p>25 correct you would be looking, usually, at more</p>	<p style="text-align: right;">Page 72</p> <p>1 MS. AHERN: I'm not finished with my</p> <p>2 question. You can object when I'm done with my</p> <p>3 question.</p> <p>4 MR. ROTMAN: I object to you asking a</p> <p>5 question --</p> <p>6 MR. KLATT: She didn't have --</p> <p>7 MR. ROTMAN: -- when she's asking --</p> <p>8 MS. AHERN: I can ask a question</p> <p>9 whenever I want. She doesn't have to answer the</p> <p>10 question if you instruct her not to, but while</p> <p>11 she's spending time looking through her report,</p> <p>12 I'm going to ask her a different question based</p> <p>13 on her recollection.</p> <p>14 MR. ROTMAN: Well, you've asked her a</p> <p>15 question, she's in the process of answering it,</p> <p>16 and you're asking -- you're asking her a second</p> <p>17 question. That's what I'm objecting to.</p> <p>18 BY MS. AHERN:</p> <p>19 Q. Doctor --</p> <p>20 MR. ROTMAN: Let her finish --</p> <p>21 Q. -- can you answer the question without</p> <p>22 looking at your report?</p> <p>23 A. Well, I'd like to refer to my report if</p> <p>24 you're asking questions.</p> <p>25 Q. And that's fine. My only question,</p>
<p style="text-align: right;">Page 71</p> <p>1 slide if there's more tissue that would fit in</p> <p>2 one cassette to make one slide.</p> <p>3 Q. Let's talk about high-grade serous</p> <p>4 carcinoma.</p> <p>5 High-grade serous carcinoma is the most</p> <p>6 common form of ovarian cancer; correct?</p> <p>7 A. It's most -- yes.</p> <p>8 Q. By far the most common form of ovarian</p> <p>9 cancer; is that also correct?</p> <p>10 A. It's the most common form, yes.</p> <p>11 Q. So let's talk about high-grade serous</p> <p>12 carcinoma in the context of chronic inflammation.</p> <p>13 Do you know of any published literature that</p> <p>14 connects chronic inflammation causally with the</p> <p>15 development of high-grade serous carcinoma?</p> <p>16 A. I can -- in my report, I actually do</p> <p>17 have a section. Let me find it.</p> <p>18 MR. ROTMAN: It might be easier to take</p> <p>19 off the clip, if that helps you flip the pages,</p> <p>20 because it's two-sided.</p> <p>21 Q. Doctor, while you look for that, just</p> <p>22 to the best of your recollection, do you remember</p> <p>23 reading any studies that concluded that --</p> <p>24 MR. ROTMAN: I object. She's in the</p> <p>25 middle of answering --</p>	<p style="text-align: right;">Page 73</p> <p>1 really, was, just based on your recollection as</p> <p>2 we sit here discussing chronic inflammation and</p> <p>3 ovarian cancer, if you are aware of studies that</p> <p>4 causally associate chronic inflammation with</p> <p>5 high-grade serous carcinoma?</p> <p>6 A. So there's definitely literature that</p> <p>7 has looked at associations between chronic</p> <p>8 inflammation and the resulting sort of</p> <p>9 expressions.</p> <p>10 And that's what -- I was trying to point you</p> <p>11 to my report on Page 12, the end of it, where it</p> <p>12 says, "There also is evidence that talc induces</p> <p>13 macrophage TNF alpha expression and macrophages</p> <p>14 that express TNF alpha promote ovarian tumor</p> <p>15 genesis. TNF alpha is involved in chronic</p> <p>16 inflammation and induces mutations in vitro and</p> <p>17 TNF alpha-induced chromosomal mutations occur</p> <p>18 mostly in cells with P53 aberrations and, of</p> <p>19 note, high-grade serous carcinomas typically have</p> <p>20 inactivating mutations in P53."</p> <p>21 So, again, we don't know all the mechanisms</p> <p>22 of all of these tumors, but there's certainly</p> <p>23 literature that is investigating those types of</p> <p>24 associations.</p> <p>25 MR. KLATT: Object. Nonresponsive.</p>

<p style="text-align: right;">Page 74</p> <p>1 MS. AHERN: Same.</p> <p>2 Q. But since you brought it up, on Page 12</p> <p>3 of your report, can you translate for me that</p> <p>4 paragraph that you just read and put it in lay</p> <p>5 terms and explain how that has anything to do</p> <p>6 with causal associations with ovarian cancer and</p> <p>7 chronic inflammation caused by talc?</p> <p>8 MR. ROTMAN: Objection.</p> <p>9 A. Well, I think it's there in the report.</p> <p>10 If talc is inducing macrophage TNF alpha</p> <p>11 expression and macrophages that express TNF alpha</p> <p>12 can promote ovarian tumor genesis that occur</p> <p>13 mostly in the -- TNF alpha-induced chromosomal</p> <p>14 mutations occur mostly in cells with P53</p> <p>15 aberrations, I think that's relevant in looking</p> <p>16 at evidence that -- for a plausible mechanism</p> <p>17 that inflammation caused by talc can cause</p> <p>18 aberrations in -- can cause P53 aberrations. And</p> <p>19 we know that high-grade serous carcinomas, many</p> <p>20 of them have P53 mutations.</p> <p>21 Q. And high-grade serous carcinomas with</p> <p>22 P53 mutations, what causes the P53 mutations?</p> <p>23 A. Well, again, the literature is still</p> <p>24 evolving into all of the mechanisms regarding</p> <p>25 this. Some of them we know are sort of aberrant</p>	<p style="text-align: right;">Page 76</p> <p>1 genomic event in the development of high-grade</p> <p>2 serous carcinoma?</p> <p>3 A. So, again, I don't know if I -- I don't</p> <p>4 know if we always know what the earliest</p> <p>5 identifiable genomic event in the development of</p> <p>6 high-grade serous carcinoma is.</p> <p>7 Q. Have you reviewed the literature on</p> <p>8 high-grade serous carcinoma from a molecular</p> <p>9 genetics perspective?</p> <p>10 A. Yes, I reviewed papers on molecular</p> <p>11 genetics, yes.</p> <p>12 Q. Do those papers indicate that one of</p> <p>13 the earliest, if not the earliest, genomic event</p> <p>14 in the development of high-grade serous carcinoma</p> <p>15 that has been identified are mutations in P53?</p> <p>16 A. So, again, you can see P53 mutations,</p> <p>17 for example, in the fallopian tubes and you can</p> <p>18 have sort of serous tubal intraepithelial</p> <p>19 carcinomas in the fallopian tube, which are</p> <p>20 thought to be early precursors for high-grade</p> <p>21 carcinoma.</p> <p>22 Q. High-grade serous carcinoma?</p> <p>23 A. Mm-hmm. Sorry, high-grade serous</p> <p>24 carcinoma.</p> <p>25 Q. And do you agree that the STIC lesions</p>
<p style="text-align: right;">Page 75</p> <p>1 mutations, and we don't always know why they</p> <p>2 occur.</p> <p>3 We know that women with BRCA1 and BRCA2</p> <p>4 mutations have -- can get high-grade -- have a</p> <p>5 higher risk of high-grade serous carcinoma.</p> <p>6 But, again, I don't think we know all of the</p> <p>7 mechanisms that cause, you know, all of these</p> <p>8 tumors.</p> <p>9 MS. AHERN: Objection. Nonresponsive.</p> <p>10 Q. Doctor, do you know, as we sit here</p> <p>11 today, what causes P53 mutations in high-grade</p> <p>12 serous carcinoma?</p> <p>13 A. I think I answered that. We know, I</p> <p>14 mean, what's in my report and women with BRCA1</p> <p>15 and BRCA2 mutations. But, again, the literature</p> <p>16 is evolving with this.</p> <p>17 Q. Doctor, are you suggesting that BRCA1</p> <p>18 and -2 mutations cause P53 mutations in</p> <p>19 high-grade serous carcinomas?</p> <p>20 A. What I'm saying is that we know that</p> <p>21 BRCA1 and BRCA2 mutation patients have a high</p> <p>22 risk of ovarian cancer.</p> <p>23 And so you're asking me what causes, so, you</p> <p>24 know, I'm telling you the data that we have.</p> <p>25 Q. What is the earliest identifiable</p>	<p style="text-align: right;">Page 77</p> <p>1 or serous tubal epithelial carcinomas in the</p> <p>2 fallopian tubes are currently known to be the</p> <p>3 earliest manifestation of high-grade serous</p> <p>4 carcinoma?</p> <p>5 A. Well, it depends on what you mean by</p> <p>6 "manifestation." I mean, it takes a period of</p> <p>7 time from initial insult until we can recognize</p> <p>8 something histologically as a precursor to</p> <p>9 cancer.</p> <p>10 Q. That was -- you're right, that was a</p> <p>11 bad question.</p> <p>12 Do you recognize serous tubal</p> <p>13 intraepithelial carcinomas as an in situ serous</p> <p>14 carcinoma?</p> <p>15 A. I think evidence is supportive of</p> <p>16 serous tubal intraepithelial carcinomas being a</p> <p>17 precursor to some high-grade serous carcinomas.</p> <p>18 Q. And when you say "precursor," do you</p> <p>19 mean a frank cancer or a premalignant lesion?</p> <p>20 What do you mean by "precursor"?</p> <p>21 A. Well, again, not -- we don't know if</p> <p>22 all STICs are going to become high-grade serous</p> <p>23 carcinomas. STICs were originally discovered in</p> <p>24 looking at fallopian tubes of BRCA1 and BRCA2</p> <p>25 patients that had -- what's the word I'm looking</p>

<p style="text-align: right;">Page 78</p> <p>1 for? -- prophylactic salpingectomies to decrease 2 their risk of ovarian cancer.</p> <p>3 And that was -- you know, they had evaluated 4 these precursor lesions, and so the thought is 5 that when you have these atypical cells in the 6 fallopian tube fimbria that are -- that have P53 7 aberrations, that that -- the belief is that 8 that's a precursor to some of the serous invasive 9 carcinomas that we see.</p> <p>10 Q. Do you consider STIC lesions to be 11 carcinomas?</p> <p>12 A. They're -- the name is intraepithelial 13 carcinoma, so its analogous term would be sort of 14 an in situ cancer.</p> <p>15 Q. It is a cancer; correct?</p> <p>16 A. Well, they're calling them 17 intraepithelial carcinomas because they have -- I 18 mean, it's sort of semantics. They have a P53 19 mutation and they're recognizable histologically.</p> <p>20 Q. Do you agree that they're carcinomas or 21 cancer?</p> <p>22 A. I certainly agree that they can be 23 precursors to invasive serous carcinomas. It's 24 sort of semantics, precursor -- it -- it's -- 25 it's sort of the same question as ductal</p>	<p style="text-align: right;">Page 80</p> <p>1 that ovulation event, you might end up with 2 precursors.</p> <p>3 We don't really have a model in a lot of 4 ovarian cancers where you can follow a precursor 5 all the way through to -- what we think is a 6 precursor all the way through to the final tumor. 7 We just -- we don't really have a lot of data on 8 those in-between steps.</p> <p>9 So it was very, very interesting when they 10 discovered these STIC lesions in the fallopian 11 tube fimbria that had P53 mutations. It was 12 pretty compelling that these might be the 13 precursor lesions to serous -- high-grade serous 14 carcinomas.</p> <p>15 Now, are all high-grade serous carcinomas 16 caused by STIC lesions or are they all -- is a 17 STIC lesion a precursor to all serous -- 18 high-grade serous carcinomas? I don't think we 19 know that.</p> <p>20 Q. Do you know of any data associating 21 high -- excuse me, associating chronic 22 inflammation or injury with the development of 23 STIC lesions?</p> <p>24 A. So, again, I think the literature is 25 still evolving with this -- these STIC lesions.</p>
<p style="text-align: right;">Page 79</p> <p>1 carcinoma in situ in the breast. There's 2 literature that debate about is ductal carcinoma 3 in situ a true cancer or is it a risk factor for 4 cancer, and what is the meaning of treatment for 5 DCIS in the breast? And I would say that that's 6 sort of analogous to STIC lesions in the 7 fallopian tube.</p> <p>8 Q. Okay. Do you agree that most 9 high-grade serous carcinomas arise from the 10 endometrial cells in the fallopian tube?</p> <p>11 A. High-grade --</p> <p>12 Q. Epithelial cells in the fallopian tube. 13 Excuse me.</p> <p>14 A. So, again, we -- this was something 15 that the medical community really struggled with, 16 trying to find the precursor lesions to a lot of 17 these tumors.</p> <p>18 And for a lot of years it was thought that 19 maybe serous carcinomas derived from what are 20 called epithelial inclusion cysts, so, basically, 21 the thought was that during ovulation, you're 22 disrupting the surface epithelium of the ovary 23 and when the ovary sort of heals itself, you get 24 this invaginated epithelium within the ovary and 25 that maybe because of inflammatory response to</p>	<p style="text-align: right;">Page 81</p> <p>1 Q. Sorry. Were you finished? I don't 2 want to interrupt you if you're thinking.</p> <p>3 A. No, I'm thinking.</p> <p>4 Again, I don't think we really have the data 5 on where these STIC lesions are coming from.</p> <p>6 Q. As part of your literature review for 7 your MDL report, did you search specifically for 8 papers that might be linking or associating 9 chronic inflammation with early precursor lesions 10 to serous invasive carcinomas or high-grade 11 serous carcinomas?</p> <p>12 A. I was certainly looking for literature 13 with the association of inflammation with ovarian 14 cancer.</p> <p>15 Q. With -- did you look specifically at 16 the various subtypes of ovarian cancer?</p> <p>17 A. Yes.</p> <p>18 Q. Is there a particular subtype of 19 ovarian cancer that you think is associated with 20 talc use?</p> <p>21 A. So most of the epidemiology literature 22 show the highest association with high-grade 23 serous invasive carcinoma.</p> <p>24 Q. When you say "highest association," are 25 you talking about strength of association?</p>

<p style="text-align: right;">Page 82</p> <p>1 A. I'm talking about the -- for example, 2 on the cohort studies, they found an association 3 with high-grade serous carcinoma. 4 And in a lot of the case-control studies, 5 when they looked at tumor subtype, a lot of those 6 tumors were serous carcinomas. Now, some of them 7 broke them out by relative risk by subtype; some 8 of them didn't. I'd have to look at the papers. 9 Q. Do you remember which cohort study 10 found an association with high-grade serous 11 carcinoma? 12 A. I believe the Nurses' Health Study. 13 I'd have to look at it to see the numbers. 14 Q. Was there more than one cohort study 15 that you recall associated talc use with 16 high-grade serous carcinoma? 17 A. I'd have to look at them just to be 18 sure, but the one that I remember is the Nurses' 19 Health Study. 20 Q. Are there any other subtypes, 21 histologic types, of ovarian cancer that you 22 believe are associated with talc use? 23 A. Well, I think talc use -- I think talc 24 use could be associated with the -- any type of 25 surface epithelial cancer. That seems to bear</p>	<p style="text-align: right;">Page 84</p> <p>1 A. So I think the most consistent finding 2 is with high-grade serous carcinoma, but there's 3 data for the other types of surface epithelial 4 carcinomas. 5 Q. And what are the surface types of 6 carcinomas? 7 A. So they're endometrioid and clear cell, 8 and mucinous less so than, I believe, the 9 endometrioid and clear cell, although I believe, 10 again, in the 2010 Nurses' Health -- is that -- 11 I'd have to go back -- I -- there was a mention 12 of mucinous -- I'm not absolutely sure it was the 13 Gates 2010, but there was a mention of an 14 increased risk of mucinous in one of those 15 studies. 16 Q. Do you agree that the different 17 histologic subtypes of epithelial ovarian cancer 18 are likely to have different genetic causes? 19 A. I know they're associated with 20 different genetic mutations. 21 Q. Do they develop along distinct 22 molecular genetic pathways? 23 A. That's what the literature suggests at 24 this point. 25 Q. Do they behave differently?</p>
<p style="text-align: right;">Page 83</p> <p>1 out in the epi data. They've certainly seen an 2 association with different types of surface 3 epithelial cancers in the epi data, the strongest 4 association being with the serous invasive. 5 Q. Have you seen any data supporting an 6 association with talc use and a low-grade serous 7 carcinoma? 8 A. I'd have -- again, I'd have to look at 9 the different studies to break it out, but I know 10 there was a study that found an increased risk 11 with serous borderline carcinomas. I'd have to 12 look through the individual data sets. 13 Q. And serous borderline -- are -- serous 14 borderline tumors are not carcinomas; correct? 15 A. Sorry. I -- serous borderline tumors, 16 yes. I misspoke. 17 Q. And you don't remember what study that 18 was that associated talc use with serous 19 borderline tumors? 20 A. I would have to look at the data -- or 21 the study. 22 Q. So do your opinions in this case apply 23 equally to all histologic subtypes of ovarian 24 cancer or are there specific subtype or subtypes 25 that you are opining are caused by talc?</p>	<p style="text-align: right;">Page 85</p> <p>1 A. So the high-grade surface epithelial 2 carcinomas have a more aggressive pathway or 3 presentation. The low-grade surface endothelial 4 carcinomas tend to have a more indolent 5 progression. 6 Q. You've used the term "surface 7 epithelial carcinomas" and I haven't seen that 8 term generally used in the literature. 9 When you talk about surface epithelial 10 carcinomas, are you talking about serous or are 11 you talking about endometrioid or are you talking 12 about clear cell? Mucinous? 13 A. Epithelial carcinomas. 14 Q. That would encompass all of those, 15 wouldn't it? Wouldn't surface epithelial 16 carcinomas encompass mucinous, clear cell, 17 endometrioid, and serous subtypes? They're all 18 epithelial ovarian cancers; correct? 19 A. Yes. That's what I'm referring to when 20 I -- because we also have germ cell tumors and 21 stromal tumors of the ovary. Those are much more 22 rare, and I'm not -- you know, I don't think 23 there's associations with those. So, yes, we're 24 talking about epithelial carcinomas, to be clear. 25 Q. Well, and just -- because I want to</p>

<p style="text-align: right;">Page 86</p> <p>1 make sure your testimony is also clear.</p> <p>2 So if we could, if you could use the</p> <p>3 specific subtype names, like serous or</p> <p>4 endometrioid --</p> <p>5 A. Okay.</p> <p>6 Q. -- or clear cell. That way there's no</p> <p>7 confusion later on about what you intended.</p> <p>8 So when you say -- let's see. Let me go</p> <p>9 down. Sorry.</p> <p>10 When you say "high-grade surface epithelial</p> <p>11 carcinomas," are you talking about high-grade</p> <p>12 serous carcinomas?</p> <p>13 MR. ROTMAN: Objection. You're asking</p> <p>14 her to reflect back on all of her prior answers</p> <p>15 to all of your prior questions, whether she was</p> <p>16 referring to the same thing in each one?</p> <p>17 Q. Do you understand my question?</p> <p>18 A. I'd have to figure out what answer</p> <p>19 you're talking about, but --</p> <p>20 Q. So you just -- just a few questions</p> <p>21 ago, you answered -- I said, "Do the different</p> <p>22 types -- histologic types develop along the same</p> <p>23 molecular genetic pathways?"</p> <p>24 You said, "That's what the literature</p> <p>25 suggests at this point."</p>	<p style="text-align: right;">Page 88</p> <p>1 Does that make sense?</p> <p>2 A. Okay. Yes. Okay.</p> <p>3 Q. Okay. All right. So let me ask my</p> <p>4 question that I asked a little while again, and</p> <p>5 you tell me -- you can answer it again with the</p> <p>6 terminology.</p> <p>7 Do the different histologic subtypes of</p> <p>8 ovarian cancer behave differently?</p> <p>9 A. Yes. Again, the high-grade ones</p> <p>10 generally behave differently than the low-grade</p> <p>11 ones.</p> <p>12 Q. Okay. Do endometrioid and clear cell</p> <p>13 carcinomas behave differently from high-grade</p> <p>14 serous carcinomas?</p> <p>15 A. The high-grade serous carcinomas tend</p> <p>16 to behave more aggressively.</p> <p>17 Q. Do low-grade serous carcinomas behave</p> <p>18 differently from endometrioid, clear cell, and</p> <p>19 high-grade serous carcinomas?</p> <p>20 A. They tend to be less aggressive. They</p> <p>21 all tend to be less aggressive than the</p> <p>22 high-grade serous carcinomas or other high-grade</p> <p>23 carcinomas of the ovary.</p> <p>24 Q. And are they thought to each have</p> <p>25 different cells of origin?</p>
<p style="text-align: right;">Page 87</p> <p>1 I asked, "Do they behave differently?"</p> <p>2 And then you responded, "So the high-grade</p> <p>3 surface epithelial carcinomas have a more</p> <p>4 aggressive pathway or presentation. The</p> <p>5 low-grade surface epithelial carcinomas tend to</p> <p>6 have a more indolent..."</p> <p>7 Were you talking about high-grade serous and</p> <p>8 low-grade serous carcinomas?</p> <p>9 A. I was talking -- sorry. I was talking</p> <p>10 about high-grade serous carcinomas, yeah. And we</p> <p>11 also have sort of undifferentiated carcinomas</p> <p>12 that are also considered high grade.</p> <p>13 Q. Okay. And were you talking about</p> <p>14 low-grade serous carcinomas when you said</p> <p>15 "low-grade surface"?</p> <p>16 A. No. So "surface" doesn't really refer</p> <p>17 to cell type; it's just sort of a --</p> <p>18 Q. Right.</p> <p>19 A. -- an umbrella term for the epithelial</p> <p>20 carcinoma.</p> <p>21 Q. Right, which is my point. I just</p> <p>22 wanted to be clear. When you say "surface" --</p> <p>23 A. Yes.</p> <p>24 Q. -- could you instead use the actual</p> <p>25 cell type.</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Again, we're not entirely sure where</p> <p>2 these tumors are arising from, particularly with</p> <p>3 mucinous carcinomas. I think mucinous carcinomas</p> <p>4 and there's also a type transitional cell, which</p> <p>5 is very, very rare, and most of the literature,</p> <p>6 when it comes to the epi data, don't really</p> <p>7 discuss transitional cell.</p> <p>8 But putting that aside, mucinous carcinomas</p> <p>9 we have, I think, the least amount of data on</p> <p>10 where they are actually arising from. Clear cell</p> <p>11 and endometrial carcinomas have an association</p> <p>12 with endometriosis, but, again, you know, are all</p> <p>13 cases of endometrioid and clear cell carcinomas,</p> <p>14 are they all arising from endometriosis? I don't</p> <p>15 think I can say that. I don't think we know for</p> <p>16 sure.</p> <p>17 And serous carcinomas, we talked about the</p> <p>18 precursor lesions and the fallopian tubes.</p> <p>19 So there are differences where we think the</p> <p>20 tumors are arising from, but, again, I don't</p> <p>21 think we have absolutes where we can definitively</p> <p>22 say, you know, this particular tumor in this</p> <p>23 particular woman arised [sic] from this precursor</p> <p>24 or...</p> <p>25 Q. Okay. And do you know if the different</p>

<p style="text-align: right;">Page 90</p> <p>1 histologic subtypes have been associated in the 2 epidemiologic literature with different risk 3 factors? 4 A. Yes. Again, I think we touched on some 5 of that before. There is an association with 6 endometrioid and clear cell with endometriosis 7 and obesity. 8 Mucinous carcinomas have shown to be 9 associated in some studies with a smoking 10 history. 11 High-grade serous carcinomas, it's a little 12 bit harder. We know that BRCA1 and BRCA2 13 patients have an increased risk. 14 Q. Now that we're on that topic of 15 genetics, do you know what proportion -- 16 currently, what is believed to be the proportion 17 of ovarian cancers that are caused by germline 18 mutations? 19 A. Off the top of my head, I think -- do I 20 have that in my report? But I -- I'm thinking 21 it's 10 to 20 percent, but that's off the top of 22 my head. 23 Q. Have you seen any research coming out 24 of Seattle Cancer Care Alliance over the last 10 25 or 15 years that indicates the number could be as</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. -- this is an article by Karen 2 Malmberg, et al., entitled "Serous tubal 3 intraepithelial carcinoma, chronic fallopian tube 4 injury, and serous carcinoma development," and it 5 was in Virchows Archives, March of 2016. 6 MR. TISI: What did you mark this? I'm 7 sorry. 8 MS. AHERN: I marked this one 9. Thank 9 you. No -- yes, 9. 10 MR. TISI: Oh, I'm sorry. 11 MS. AHERN: That's okay. 12 Q. Do you recall if you've ever reviewed 13 this article? 14 A. It's possible. It's certainly possible 15 that I have seen this before in just my daily 16 practice. I don't believe I cited it in any of 17 the references that I can remember, but it's 18 highly possible that I've seen it. 19 Q. Do you see the first page that -- you 20 can just skip if you want, take your time reading 21 it if you'd like, but the authors conclude in 22 their study that there is no correlation with 23 chronic tubal injury or inflammation with the 24 development of STIC lesions or the existence of 25 STIC lesions.</p>
<p style="text-align: right;">Page 91</p> <p>1 high as a quarter of all ovarian cancers being 2 linked to germline mutations? 3 A. That would roughly fit with what I just 4 said, 10 to 20 percent. I can't say for sure 5 that I have seen that. I might have. But it 6 fits with what I remember. 7 Q. I had asked you earlier if you had 8 reviewed any literature relating to inflammatory 9 conditions and associations with early STIC 10 lesions. 11 And you -- and, I'm sorry, I don't want to 12 misstate your response. What was your response 13 to that? 14 A. Had I reviewed literature? Yes, I've 15 seen literature. 16 Q. Okay. 17 (Article entitled "Serous tubal 18 intraepithelial carcinoma, chronic 19 fallopian tube injury, and serous carcinoma 20 development" marked Exhibit 9.) 21 BY MS. AHERN: 22 Q. I'm handing you what's been marked as 23 Exhibit 9 to your deposition. And this is -- 24 MS. AHERN: I don't know if anyone else 25 wants one.</p>	<p style="text-align: right;">Page 93</p> <p>1 Do you see that? 2 A. No. Can you -- I'm sorry, can you 3 point to me -- 4 Q. Oh, sure. 5 A. -- where? 6 Q. Do you see the abstract, if you carry 7 it over to the second column? 8 A. Mm-hmm. Yes. 9 Q. It says, "STIC and invasive cancer were 10 seen more often in the older patients than in the 11 younger patients"? 12 A. Mm-hmm. 13 Q. This study is -- small study, no 14 correlation with chronic tubal injury or 15 inflammation was identified. 16 A. Yes, with the caveat -- that was a 17 conclusion with the caveat that it was a small 18 study. 19 Q. Have you -- as a gynecologic 20 pathologist or a pathologist who has subspecialty 21 training in gynecologic malignancies, how often 22 do you see chronic -- or evidence of chronic 23 inflammation surrounding STIC lesions? 24 Or strike that. How often do you see STIC 25 lesions?</p>

<p style="text-align: right;">Page 94</p> <p>1 A. On -- certainly, I can't give you a 2 number. I've certainly made the diagnosis and 3 see it -- I can't give you a number of how many 4 times. 5 Q. Have you ever been involved in a study 6 looking specifically at STIC lesions and 7 high-grade serous carcinomas? 8 A. I have not been involved in a study, 9 no. 10 Q. Have you ever seen evidence of chronic 11 inflammation with a STIC lesion? 12 A. Off the top of my head, I am not sure. 13 It's possible, but I can't really answer that off 14 the top of my head. 15 Q. How often do you see chronic 16 inflammation in the fallopian tubes associated 17 with high-grade serous carcinoma? 18 A. You can certainly see it, but it sort 19 of goes along with the discussion that we had 20 before. You can see chronic inflammation within 21 the tumor, as well. 22 And so I think, you know, the literature 23 is -- the research is ongoing as to, you know... 24 Q. So once the tumor -- once there's a lot 25 of tumor burden in the abdominal cavity, it's</p>	<p style="text-align: right;">Page 96</p> <p>1 looks -- 2 MR. ROTMAN: Just so the record is 3 clear, when you said "this," do you want to 4 identify it? 5 A. Sorry. The fourth edition belongs to a 6 colleague. The fifth edition is my own. 7 MS. AHERN: Okay. We'll get to that 8 one. I'll mark that next. 9 Q. There is a photocopy here, "Blaustein's 10 Pathology of the Female Genital Tract, Fourth 11 Edition," Pages 300 and -- well, Page 376, 12 Page 539, Page 540, 648, 1216, 1217, 1218. 13 Is this a copy -- are these copies that you 14 made? 15 A. Yes. 16 Q. Okay. 17 MR. TISI: Do you have a stapler? 18 Otherwise I'll get one. 19 MS. AHERN: No, I don't have one. 20 MR. TISI: No, I'll go get one. 21 BY MS. AHERN: 22 Q. Can you tell me why you made those 23 copies? 24 A. I made them because it was easier than 25 lugging around a whole textbook. That's why I</p>
<p style="text-align: right;">Page 95</p> <p>1 difficult to tell where the inflammation is 2 coming from or what started it; is that correct? 3 A. Well, if there's chronic inflammation 4 in the tumor, it's likely the tumor has something 5 to do with the chronic inflammation. 6 But, again, you know, as we talked about 7 before, I think sometimes it is difficult to 8 tell. 9 MS. AHERN: Okay. Housekeeping matters 10 before I forget. 11 Let me go ahead somehow and mark -- 12 let's mark -- we can remove this later -- 13 "Blaustein's Pathology of the Female Genital 14 Tract," Fourth Edition, as Exhibit 10 to your 15 deposition. 16 ("Blaustein's Pathology of the 17 Female Genital Tract," Fourth Edition, 18 marked Exhibit 10.) 19 BY MS. AHERN: 20 Q. And, Doctor, you brought this textbook 21 with you today. 22 Is this your textbook? 23 A. That particular copy is not. That's my 24 coworker's copy. This copy is mine (indicating). 25 Q. Okay. And inside this, you have what</p>	<p style="text-align: right;">Page 97</p> <p>1 Xeroxed them. But -- 2 Q. You had to bring it anyway. 3 Sorry. Go ahead. 4 A. But the particular pages that I copied 5 are ones that talk about granulomatous reactions 6 to talc in the female reproductive system. 7 Oh, sorry. Okay. 8 MS. AHERN: Okay. We'll go ahead and 9 mark those copies as Exhibit 10 to your 10 deposition. 11 Q. And just to confirm -- 12 MS. AHERN: Sorry. Are we on 10 or 11? 13 We're on 11. Thank you. 14 Q. As a -- 15 MR. TISI: Is this the next one? 16 MS. AHERN: Yeah. Hold on. I'm going 17 to clarify it. 18 Q. So this photocopy that you made from 19 Blaustein's came from the fourth edition? 20 A. Correct. 21 Q. The textbook that we have here marked 22 as Exhibit 10. 23 A. (Witness nodded.) 24 Q. Okay. So Exhibit 11 are photocopies of 25 specific pages from Exhibit 10, which is</p>

<p style="text-align: right;">Page 98</p> <p>1 Blaustein's Pathology of the Female Genital 2 Tract, Fourth Edition. 3 (Excerpt from "Blaustein's 4 Pathology of the Female Genital Tract," 5 Fourth Edition, marked Exhibit 11.) 6 BY MS. AHERN: 7 Q. Okay. And can you tell me, with 8 Exhibit 11, the specific information that you 9 found relevant to your opinions in this case? 10 A. Okay. So on Page -- 11 MR. ROTMAN: You marked the copy as 12 Exhibit 11 and the book as Exhibit 10? 13 MS. AHERN: Mm-hmm. 14 MR. ROTMAN: Okay. 15 A. Okay. You have to bear with me, 16 because I don't have any highlights or anything, 17 so I have to find it. 18 So Page 376, right down -- okay. The last 19 paragraph under "Zanko Granulomatous 20 Inflammation," it says, "Rarely, talc or another 21 foreign substance may elicit a foreign-body 22 reaction in the endometrium. Talc may be 23 introduced into the endometrial cavity by 24 instruments contaminated with talcum powder or by 25 gloves during a pelvic examination. Patients may</p>	<p style="text-align: right;">Page 100</p> <p>1 evidence, and it shows that talc can cause 2 granulomatous or chronic inflammation in the 3 female reproductive tract. 4 Q. And how is uterine cancer related to, 5 for instance, high-grade serous carcinoma of the 6 ovary? 7 A. Again, this is just evidence that talc 8 can cause chronic inflammation and granulomas in 9 the endometrium, which I think is another piece 10 of evidence that talc can cause chronic 11 inflammation and granulomatous inflammation in 12 the female reproductive tract. 13 Q. Doctor, shouldn't talc -- based on the 14 literature that we have available to us over the 15 last 50 years, shouldn't talc induce that 16 response in any tissue that it's found in? 17 A. Well, again, different tissues will 18 respond in different ways, but I think it also 19 depends -- well, I'll just... 20 Q. Well, as a pathologist -- 21 MR. ROTMAN: Wait. Wait. Are you 22 done? 23 MS. AHERN: Are you done? 24 THE WITNESS: I think so. 25 Q. Okay. So as an anatomic pathologist</p>
<p style="text-align: right;">Page 99</p> <p>1 be asymptomatic or may have menorrhagia. 2 Microscopically, the extent of the granulomatous 3 inflammatory reaction depends on the quantity of 4 talc inoculated. The infiltrate is characterized 5 by histiocytes and foreign-body multinucleated 6 giant cells surrounding the talc crystals, along 7 with lymphocytes and plasma cells. The crystals 8 appear as refractile, birefringent, needle-like, 9 or fan-shaped splinters in polarizing light." 10 Then on Page 530 -- 11 Q. Sorry. Let me just -- let's take this 12 in order. 13 So what about that particular passage 14 informs your causation opinions regarding talc 15 and ovarian cancer, if at all? 16 A. So it is evidence that talc causes 17 foreign-body giant cell reaction and chronic 18 inflammation in the endometrium. 19 Q. And that is the uterine tissue; 20 correct? 21 A. That's the lining of the uterus, 22 correct. 23 Q. And how does that inform your opinions 24 regarding the development of ovarian cancer? 25 A. Well, I thought, again, it's a piece of</p>	<p style="text-align: right;">Page 101</p> <p>1 who knows something about granulomatous 2 reactions, shouldn't a foreign body produce a 3 foreign-body reaction in any tissue that it's 4 found in? 5 A. Not -- no, not always. Sometimes you 6 will have a foreign body that won't cause a 7 foreign-body giant cell reaction. It depends 8 on -- it depends on the particle, the foreign 9 body, the tissue it's in. You don't always see 10 that. And also the timing, when you're looking 11 at it, versus how long it's been there. 12 Q. Well, the timing is just more or less 13 when you observed it, not whether it occurred; 14 correct? 15 MR. ROTMAN: Objection. 16 A. So it's hard to know whether or not it 17 occurred -- if it had been there for a long time 18 and you're looking years, you know, in -- years 19 after it's been there, if you don't see a 20 granulomatous or chronic inflammation, that's not 21 evidence that it never occurred; it's just you're 22 not seeing it at that moment. 23 Q. Do you know of any -- any foreign 24 bodies that generate tissue-specific reactions? 25 A. Well, we -- I mean, we certainly have</p>

<p style="text-align: right;">Page 102</p> <p>1 evidence with, say, viruses and bacteria that 2 respond differently -- certain tissues will 3 respond differently to different infections. 4 For esophageal cancer, there's some 5 literature to suggest that very hot liquids 6 increase your risk of esophageal cancer. So, 7 yes, certain tissues will respond differently to 8 different material. 9 Q. So my question was -- it might be just 10 a little simpler to think of just this 11 question -- do you know of any foreign bodies -- 12 I'm not talking about viruses and bacteria which 13 cause immune responses -- but foreign bodies that 14 generate a tissue-specific foreign-body reaction? 15 A. Well, it's sort of semantics. I mean, 16 viruses and bacteria -- that's why I answered the 17 way I did -- are foreign to -- and, certainly, 18 foreign bodies can elicit immune response. 19 That's why you see granulomatous reactions and 20 chronic inflammation. 21 So I guess I'm not -- I think I answered the 22 question. 23 Q. Pathologists distinguish the different 24 types of granulomatous inflammation based on the 25 cause of the inflammation; correct?</p>	<p style="text-align: right;">Page 104</p> <p>1 granulomas, which are caused by talc and 2 cornstarch and certain other inert-type 3 materials; correct? 4 MR. ROTMAN: Objection. 5 A. Again, you can have inflammation -- 6 granulomatous inflammation due to infection, you 7 can have granulomatous infection -- response due 8 to foreign bodies, and you can have granulomas in 9 certain diseases, like sarcoidosis or Crohn's 10 disease. 11 So in that respect, yes, we're categorizing 12 granulomas, but on a daily basis, other than that 13 type of breakdown, we're not subcategorizing 14 granulomas. 15 Q. But you are aware of the literature 16 that actually characterizes the different types 17 of granulomas and the types of cells that are 18 involved in the formation of those granulomas; 19 correct? 20 A. As far as foreign-body giant cells and 21 multinucleated giant cells and inflammatory 22 versus foreign body, yes. 23 Q. So, you know, a granuloma caused by 24 tuberculosis is going to be very different from a 25 granuloma caused by talc; correct?</p>
<p style="text-align: right;">Page 103</p> <p>1 A. We look for -- if we see granulomatous 2 inflammation in tissue, we certainly look for a 3 potential cause. We want to rule out infection, 4 so if we see granulomas, we'll routinely do 5 special stains to rule out infection. Like we'll 6 do an acid-fast Bacillus stain for microbacteria. 7 We'll do fungal stains to rule out a fungal 8 infection that causes inflammation. 9 And then, of course, if we have -- if those 10 are negative and we're trying to figure out if 11 there's a foreign body within a granuloma, we can 12 use polarized light to try to find the foreign 13 body to identify it as a foreign-body giant cell 14 reaction. 15 But often you do have granulomatous 16 inflammation and you won't find fungi -- fungal 17 lesions -- fungal bodies or bacteria or 18 birefringent particles on them, so you don't 19 necessarily know why you have a granulomatous 20 inflammation. 21 Q. Pathologists categorize granulomatous 22 inflammation, don't they? They categorize it in 23 terms of the different types of immune granulomas 24 and the etiologic agents for those granulomas, 25 and over here somewhere are the foreign-body</p>	<p style="text-align: right;">Page 105</p> <p>1 MR. ROTMAN: Objection. 2 A. I would say not necessarily. In 3 microbacterial infections, you can have necrosis 4 within granulomas, but that doesn't mean that 5 you're not necessarily going to see necrosis in a 6 foreign-body granuloma. 7 Q. How often have you seen necrosis 8 associated with a foreign-body granuloma? 9 A. I'd say more commonly you see 10 necrotizing or necrotic granulomas in infectious 11 granulomas. 12 Q. There are different types of 13 macrophages that are involved, too, in 14 foreign-body granulomas and in immune granulomas; 15 correct? 16 A. As far as macrophages themselves and 17 multinucleated giant cells that can form 18 granulomas. 19 Q. There are different types, different 20 subtypes of macrophages that are involved in -- 21 A. Yes. 22 Q. -- those activities; correct? 23 A. Yes. 24 Q. Okay. So there are differences between 25 a foreign-body granuloma and an immune granuloma?</p>

<p style="text-align: right;">Page 106</p> <p>1 A. There can be.</p> <p>2 Q. Well, there are, aren't there? I mean,</p> <p>3 there are papers that characterize these.</p> <p>4 A. Yes, but I'm -- yes. In the</p> <p>5 literature, yes. And -- but are we necessarily</p> <p>6 categorizing them when we're looking at a</p> <p>7 particular patient? We're looking for the cause</p> <p>8 of the granuloma, but we're not necessarily</p> <p>9 subcategorizing, is my point.</p> <p>10 Q. Understood.</p> <p>11 Oh, I'm sorry. We were talking about the</p> <p>12 pages that you copied from Blaustein's.</p> <p>13 What was the second page in that photocopy,</p> <p>14 Exhibit 11?</p> <p>15 A. Okay. So Page 539.</p> <p>16 Q. What was it on 539 that's relevant to</p> <p>17 your opinions in this case?</p> <p>18 A. Okay. I think it starts at the very</p> <p>19 bottom. I think it carries into Page 540, where</p> <p>20 it starts talking about foreign-body reactions in</p> <p>21 the -- this is diseases of the fallopian tube.</p> <p>22 So it starts, "Foreign material may be</p> <p>23 introduced into the tube in the course of</p> <p>24 gynecological investigation, especially</p> <p>25 hysterosalpingography, lubricant jelly, mineral</p>	<p style="text-align: right;">Page 108</p> <p>1 cancer, which is sort of the plausibility arm of</p> <p>2 the Bradford Hill. I think it's compelling</p> <p>3 evidence that we see that you can get</p> <p>4 granulomatous inflammation and some of these</p> <p>5 sections have mentioned lymphocytes and plasma</p> <p>6 cells in the tissue. I mean, I think it's a</p> <p>7 further piece of evidence that talc can cause</p> <p>8 these -- this type of inflammation in female</p> <p>9 reproductive market.</p> <p>10 Q. How often have you, in your career,</p> <p>11 seen a talc granuloma in gynecologic specimens?</p> <p>12 A. We don't routinely do -- perform</p> <p>13 polarized light microscopy on ovarian tumors,</p> <p>14 partly because you really need electron</p> <p>15 microscopy. You can -- with polarized light</p> <p>16 microscopy, you can tell that there's a foreign</p> <p>17 substance there, but that's pretty much as far as</p> <p>18 you can -- you can get. You need more testing to</p> <p>19 be able to determine what type of particle it is,</p> <p>20 usually. So we don't, in daily practice,</p> <p>21 routinely use polarized light microscopy.</p> <p>22 Now, it's entirely possible that, you know,</p> <p>23 in the course of my career, I've come across</p> <p>24 chronic inflammation or granulomas in an ovarian</p> <p>25 tumor that could have been due to talc that I</p>
<p style="text-align: right;">Page 107</p> <p>1 oil, and starch and talc powder may cause lipoid</p> <p>2 or granulomatous salpingitis. Talc may cause</p> <p>3 mucosal or serosal granulomas. Examination of</p> <p>4 all granulomas or foreign-body reactions under</p> <p>5 polarized light is useful in the recognition of</p> <p>6 these processes."</p> <p>7 So, again, I'm just referencing the fact</p> <p>8 that talc can cause granulomatous reaction in the</p> <p>9 fallopian tube.</p> <p>10 Q. So another tissue that's exposed to</p> <p>11 talc forms the typical type of foreign-body</p> <p>12 response?</p> <p>13 A. That can form a granulomatous reaction.</p> <p>14 Q. Okay. And does that in any way inform</p> <p>15 your opinions on causation, other than</p> <p>16 granulomatous reactions occur?</p> <p>17 A. Well, so, again, it's another piece of</p> <p>18 evidence that talc can cause a granulomatous</p> <p>19 reaction within the female reproductive tract.</p> <p>20 Now, the fallopian tube, we know some -- has</p> <p>21 been indicated as a precursor site for certain</p> <p>22 high-grade serous carcinomas, so I think it's</p> <p>23 relevant.</p> <p>24 But, again, you know, we're talking about</p> <p>25 mechanisms that talc may eventually cause ovarian</p>	<p style="text-align: right;">Page 109</p> <p>1 didn't polarize so I didn't see particles, I</p> <p>2 guess.</p> <p>3 Q. So let me back up and just ask you:</p> <p>4 How often in your career have you seen</p> <p>5 foreign-body granulomas? Regardless of whether</p> <p>6 you've identified the particle in the granuloma,</p> <p>7 how often have you seen foreign-body granulomas</p> <p>8 in gynecologic specimens? Not just tumors, but</p> <p>9 any gynecologic specimens you've reviewed.</p> <p>10 A. No, I understand.</p> <p>11 Q. Okay.</p> <p>12 A. You can certainly see granulomas -- how</p> <p>13 often, I can't give you a number; that would just</p> <p>14 be wildly guessing -- but you can see granulomas</p> <p>15 in the endometrium. You can see them in</p> <p>16 different types of tumor.</p> <p>17 Sometimes it's -- you'll see granulomas, but</p> <p>18 you won't see a particle, so you don't know for</p> <p>19 sure if it's a foreign-body granuloma; you just</p> <p>20 see the granuloma because you're not using</p> <p>21 polarized light microscopy on it.</p> <p>22 MR. KLATT: Object. Nonresponsive.</p> <p>23 MS. AHERN: Same.</p> <p>24 Q. So how often, though, in your career --</p> <p>25 you can give me an estimate -- have you seen</p>

<p style="text-align: right;">Page 110</p> <p>1 foreign-body granulomas in gynecologic specimens?</p> <p>2 MR. ROTMAN: Objection.</p> <p>3 Q. I'm not talking about immune</p> <p>4 granulomas, but just foreign-body granulomas.</p> <p>5 We'll start there.</p> <p>6 MR. ROTMAN: Objection. You've asked</p> <p>7 that question. She's answered it.</p> <p>8 A. So, again, I've seen granulomas in my</p> <p>9 career in the female reproductive tract, but I</p> <p>10 don't -- pathologists don't routinely use</p> <p>11 polarized light microscopy in that instance to</p> <p>12 look for foreign bodies.</p> <p>13 Q. Okay. So are you done?</p> <p>14 MR. ROTMAN: Can we take a break?</p> <p>15 MS. AHERN: Not just yet. Let me</p> <p>16 finish this line of questioning and then we can</p> <p>17 take a break. Because we may want to -- what</p> <p>18 time is it?</p> <p>19 MR. ROTMAN: It's been an hour.</p> <p>20 MS. AHERN: 11:30. If we go a little</p> <p>21 bit longer, we can break for lunch if you want.</p> <p>22 MR. ROTMAN: I just want to take a</p> <p>23 break in the next few minutes.</p> <p>24 MS. AHERN: Sure.</p> <p>25</p>	<p style="text-align: right;">Page 112</p> <p>1 foreign body, you're not necessarily going to be</p> <p>2 able to say whether or not it's a foreign-body</p> <p>3 granuloma with absolute certainty unless you're</p> <p>4 looking under polarized light microscopy. And</p> <p>5 even then, you might not see it under polarized</p> <p>6 light microscopy, because it depends on the</p> <p>7 section of the tissue you're looking at and --</p> <p>8 Q. Okay. Thank you.</p> <p>9 And if you see a foreign-body response in</p> <p>10 tissue, do you then go one step further and</p> <p>11 polarize to see if you can identify whether</p> <p>12 that's got a foreign body in it?</p> <p>13 A. It certainly depends on the situation.</p> <p>14 So, for example, in cases where there's been</p> <p>15 a surgery and they've taken out more tissue after</p> <p>16 surgery, you might be looking for polarizable</p> <p>17 foreign body. Often, you can see a suture on</p> <p>18 light microscopy. But, yeah, we do -- depending</p> <p>19 on the situation, we will use polarized light</p> <p>20 microscopy to find foreign bodies.</p> <p>21 MR. ROTMAN: Okay.</p> <p>22 Q. How often do you polarize specimens</p> <p>23 where you've found a foreign-body response? How</p> <p>24 often do you do that?</p> <p>25 A. I think -- I think I tried to come up</p>
<p style="text-align: right;">Page 111</p> <p>1 BY MS. AHERN:</p> <p>2 Q. Doctor, are you able, as a -- as a</p> <p>3 pathologist, under regular light microscopy to</p> <p>4 identify a foreign-body granuloma? Not the</p> <p>5 content, just the foreign-body granuloma.</p> <p>6 A. I would say it depends on the specific</p> <p>7 granuloma. Sometimes, for example, in epidermal</p> <p>8 inclusion cysts, you can see the keratin under</p> <p>9 light microscopy that's causing the reaction, but</p> <p>10 you don't always -- you won't always necessarily</p> <p>11 see a particle. They're very small. And unless</p> <p>12 you're looking specifically for polarizable</p> <p>13 birefringent particles, you're not going to see</p> <p>14 it just with regular light microscopy.</p> <p>15 Q. So my question wasn't -- and I thought</p> <p>16 I was specific -- my question wasn't whether or</p> <p>17 not you could see the particle; my question was:</p> <p>18 You should be able to see the foreign-body</p> <p>19 response in terms of multinucleated giant cells.</p> <p>20 Do you -- can you see that under regular</p> <p>21 light microscopy?</p> <p>22 A. Well, so you're categorizing it as a</p> <p>23 foreign-body granuloma. What I'm saying is you</p> <p>24 can see granulomas, of course, under light</p> <p>25 microscopy. But if you're not looking for a</p>	<p style="text-align: right;">Page 113</p> <p>1 with an estimate. I think I have it in my</p> <p>2 report, actually, in the beginning.</p> <p>3 Yes. So I estimated that I use polarized</p> <p>4 light microscopy for this purpose, which is</p> <p>5 identifying foreign material to explain an</p> <p>6 inflammatory reaction, I estimated about twice a</p> <p>7 month. It's an estimate.</p> <p>8 And I -- well, that was -- actually, I was</p> <p>9 referring to calcium oxalate crystals in breast</p> <p>10 biopsies. That's different. So it's not</p> <p>11 uncommon, let's put it that way, but I can't</p> <p>12 really give you a -- an estimate.</p> <p>13 Q. What was the estimate for breast</p> <p>14 tissue?</p> <p>15 A. I think it was twice a month, is what I</p> <p>16 said.</p> <p>17 Q. So compared to looking for calcium</p> <p>18 crystals in breast tissue twice a month, how</p> <p>19 often in gynecologic specimens do you look for</p> <p>20 foreign bodies?</p> <p>21 A. I would say slightly less than that.</p> <p>22 Q. Maybe once a month, maybe less than</p> <p>23 that?</p> <p>24 A. Once a month is probably a good</p> <p>25 estimate, I guess.</p>

<p style="text-align: right;">Page 114</p> <p>1 Q. Do you know, based on your review of 2 the epidemiologic literature, what proportion of 3 women are said to use talc? 4 A. I believe I've seen in some of the 5 literature -- it depends on the population, I 6 think. I think I saw -- well, again, I'd have to 7 pull out the papers to be absolutely certain, but 8 I remember there was a reference to 9 African-American women, about 50 percent of them 10 using talc. 11 Q. Would you say that in 50 percent of the 12 gynecologic specimens you review, you find 13 foreign-body granulomas or granulomas? 14 A. Well, I wouldn't necessarily expect -- 15 I wouldn't expect to, just because, you know, 16 again, we're looking at an ovarian tumor at a 17 very particular point in time. 18 How many granulomas -- how much talc is 19 getting to the ovary, we don't -- we don't know 20 how much talc is getting to the ovary. We know 21 it's been found there, we know it can get there, 22 but we don't know with how much use, how much is 23 actually getting there. 24 So we wouldn't necessarily find a lot of 25 granulomas in ovarian tissue of women that use</p>	<p style="text-align: right;">Page 116</p> <p>1 I mean, it's not -- it's not frequent that 2 you're going to find foreign-body giant cell 3 reactions in tissue, but, again, it doesn't mean 4 that they weren't there. Maybe -- 5 Q. And this is based just on your 6 experience. I know that -- I don't want you to 7 guess about what might have been there -- 8 A. Yeah, I'm -- 9 Q. -- but based on your experience as a 10 practicing pathologist. 11 A. It would just be a pure guess at this 12 point. I couldn't give you an accurate number. 13 Q. Do you see foreign-body reactions in 14 50 percent of the gynecologic specimens or cases 15 that you review? 16 MR. ROTMAN: Objection. 17 A. I would say it's less than 50 percent. 18 Q. Is it less than 25? 19 A. I would say less than 25. 20 Q. Less than ten? 21 A. Probably less than ten. 22 Q. Less than five? 23 A. That's where I'm not exactly sure. 24 Q. Okay. 25 MS. AHERN: All right. We can go ahead</p>
<p style="text-align: right;">Page 115</p> <p>1 it, because we don't know exactly how much is 2 getting there or we don't know how long those 3 granulomas are there once the tissue is in the 4 ovary. 5 I mean, 20 years later, when you're looking 6 at the -- at the ovary for a talc particle that's 7 been there, we don't know if the granuloma would 8 still be there or the chronic inflammation would 9 still be there. 10 Q. And my question wasn't specific to 11 ovarian tissue; it was just gynecologic 12 specimens. 13 Because you review more than ovarian tissues 14 when you're looking at gynecologic samples; 15 correct? 16 A. Yes. 17 Q. So looking at all of your gynecologic 18 specimens, your vaginal, vulvar, endometrial, 19 tubal, ovarian, I guess omentum might fall in 20 there, how often do you identify foreign bodies 21 or foreign-body granulomas? 22 A. I would have to be -- a completely 23 ballpark guess, but, I don't know, maybe every -- 24 I'm really trying to figure out a somewhat 25 ballpark figure. It's tough.</p>	<p style="text-align: right;">Page 117</p> <p>1 and take a break. Thank you. 2 THE VIDEOGRAPHER: Here ends Media 2. 3 Off the record, 11:44 a.m. 4 (A recess was taken.) 5 THE VIDEOGRAPHER: Here begins Media 6 No. 3 in today's deposition of Sarah Kane, M.D. 7 Back on the record, 12:02 p.m. 8 BY MS. AHERN: 9 Q. All right. Doctor, can we go ahead and 10 keep moving through that photocopy, Exhibit 11. 11 Can you tell me what the next page was? 12 A. Okay. We just read from Page 540, I 13 believe, so the next one is Page 648. 14 Q. Okay. And tell me what on 648 caught 15 your eye. 16 A. Okay. It's the first paragraph under 17 "Noninfectious Granulomatous Peritonitis." So it 18 says, "Foreign material typically recognizable on 19 histologic examination can elicit a granulomatous 20 reaction on the peritoneum. Starch granulomas 21 from surgical gloves, douche fluid, and 22 lubricants typically incite a granulomatous and 23 fibrosing peritonitis. In occasional cases, the 24 inflammatory reaction may be a tuberculoid type 25 with KCS necrosis. The periodic acid shift (PAS)</p>

<p style="text-align: right;">Page 118</p> <p>1 positive starch granules exhibit the 2 characteristic Maltese cross configuration" -- 3 THE COURT REPORTER: I'm sorry, you're 4 reading too fast. 5 THE WITNESS: I'm sorry. 6 A. "The periodic acid shift (PAS) positive 7 starch granules exhibits a characteristic Maltese 8 cross configuration under polarized light. Talc 9 was once an important cause of granulomatous and 10 fibrosing peritonitis because of its use as a 11 lubricant on surgical gloves and talc-induced 12 peritonitis has been described more recently in 13 drug abusers." I think that's kind of where it 14 stops. 15 Q. Okay. And how does that passage that 16 you just read inform your opinions in this case? 17 A. Well, again, it's just another -- 18 similar to the last pieces, this is the 19 peritoneum, so this is outside of the fallopian 20 tube. Once particles are outside of the 21 fallopian tube, they are in the peritoneum. 22 That's where the ovary is. And so it's 23 discussing foreign-body granulomatous reactions 24 in the peritoneum. 25 Q. And this question -- this passage that</p>	<p style="text-align: right;">Page 120</p> <p>1 head. 2 Q. And when you say "they" were looking 3 at, are you talking -- who are you talking about? 4 A. When the -- when the regulatory -- if I 5 recall -- did I put that in my report? -- they 6 removed -- I know that they removed starch from 7 surgical gloves because it was causing an 8 inflammatory reaction. 9 And they had started using starch more 10 commonly because talc had been removed from 11 surgical gloves for also causing inflammatory 12 reactions. 13 Q. And talc particles and cornstarch 14 particles cause the same foreign-body reaction in 15 the peritoneum and fibrosis; correct? 16 A. Well, again, they can cause a 17 granulomatous reaction, but they're 18 bioabsorbable, so it's not going to be -- you 19 know, when we're talking about talc, we're 20 talking about the talc in surgical gloves. And, 21 you know, talc is not bioabsorbable and it will 22 stay in the peritoneum longer than starch, which 23 is bioabsorbable. So it will -- the inflammation 24 will likely resolve more quickly. It's a 25 different -- it's a different type of reaction</p>
<p style="text-align: right;">Page 119</p> <p>1 you just read also mentions that starch granules 2 from surgical gloves -- 3 A. Yes. 4 Q. -- cause granulomatous and fibrosing 5 peritonitis, which is the same that they mention 6 talc use to. 7 Would you say that starch granules, then, 8 have the capacity to cause chronic inflammation 9 that can lead to cancer? 10 A. Starch can cause inflammatory 11 reactions, but it's a -- very different, in that 12 it's bioabsorbable, and so the particles are 13 absorbed in the body. And the literature hasn't 14 supported a link between starch and ovarian 15 cancer. 16 Q. How many studies have evaluated the 17 association between starch and ovarian cancer? 18 A. I couldn't say, off the top of my head, 19 how many. But I know, you know, they looked at 20 starch when they were evaluating whether or not 21 to remove it from surgical gloves, and they ended 22 up deciding to remove it from surgical gloves. 23 And I -- I think at that point they had done 24 a literature search. I don't think there was -- 25 I don't know how many studies off the top of my</p>	<p style="text-align: right;">Page 121</p> <p>1 because it's bioabsorbable. 2 Q. Well, they both cause granulomas; 3 right? 4 A. Mm-hmm. 5 Q. And they both cause fibrosis; correct? 6 A. They can cause fibrosis. 7 Q. Does the biodurability of the causative 8 agent determine how long fibrosis exists? 9 A. Well, the fibrosis is thought to arise 10 from the inflammatory process. And since -- I 11 don't know how much data is really there except 12 to say that starch is bioabsorbable and talc is 13 not. So talc is going to be available for an 14 inflammatory response more than a starch particle 15 will. 16 Q. Is the purpose of a foreign-body 17 granuloma to essentially wall off an irritant, a 18 foreign body, from the rest of the tissue to 19 prevent damage? 20 A. That can be one reason. 21 Another reason is if the particle is large 22 enough and one macrophage can't handle it because 23 of its size, it will sort of recruit more 24 macrophages to the area to try to digest the 25 foreign material, which is not going to -- they</p>

<p style="text-align: right;">Page 122</p> <p>1 won't be able to digest the talc particle. 2 Q. If they can't digest the particle, 3 these macrophages will fuse to form a 4 multinucleated giant cell and surround the 5 particle to basically encapsulate it and prevent 6 it from harming the surrounding tissue; correct? 7 A. It's possible that they would, yes, 8 they would recruit more macrophages and 9 potentially do that. 10 Q. Isn't that the purpose of a 11 foreign-body granuloma? 12 A. So, again, you can get well-formed -- 13 you can get well-formed encapsulated granulomas. 14 You can also get sort of poorly formed granulomas 15 that are -- when more macrophages have been 16 recruited to that site. 17 You can get a -- you can get a histiocytic 18 reaction that isn't a well-formed granuloma in 19 the sense that you're talking about, where it's 20 kind of walling off the foreign body. You can 21 get histiocytic reactions that aren't as well 22 formed like that. 23 Q. But we're just talking about the actual 24 granuloma itself, those particles that do result 25 in a well-formed granuloma.</p>	<p style="text-align: right;">Page 124</p> <p>1 macrophages are continuously recruited to 2 foreign-body granulomas? 3 A. I know that I've read it in the course 4 of my daily practice. I can search at some point 5 for it, but I know that that's the case, because 6 I know that macrophages, again, have a certain 7 lifespan. 8 But, you know, again, the inflammatory 9 response, we also don't know how long that 10 inflammatory response is going to be there for 11 sure. Is it possible that at some point the 12 granuloma resolves and you get some fibrosis and 13 the talc particle or whatever particle is there 14 remains? I think that's possible and likely, in 15 fact, because you do see resolution of granulomas 16 with fibrosis. 17 Q. Is fibrosis associated with the 18 development of ovarian cancer? 19 A. There hasn't -- there hasn't been a 20 lot -- again, the causes of ovarian cancer are 21 sort of -- the literature and the research is 22 still bearing all of it out, but from what I know 23 of the literature, I don't think that they found 24 fibrosis itself being an increased risk factor 25 for ovarian cancer.</p>
<p style="text-align: right;">Page 123</p> <p>1 Once that granuloma has formed, it can 2 persist for many years, can't it, without 3 damaging the surrounding tissue? 4 MR. ROTMAN: Objection. 5 A. I think it would depend. Macrophages 6 have a certain lifespan, so it's going to be 7 constantly recruiting different macrophages to 8 that site. 9 So I don't think we can say for certain that 10 the -- in fact, I think the body is still 11 reacting to that foreign body if it's still 12 recruiting new macrophages in. 13 Q. Do you know that for a fact based on 14 your reading of the literature of granulomas, 15 that that's the mechanism behind a foreign-body 16 granuloma, as opposed to an immune granuloma? 17 A. What I'm saying is -- is that 18 macrophages have a certain shelf life, and so 19 they will constantly recruit new macrophages to 20 that area. 21 Now, whether or not there's an exposure in 22 that particle while it's in that process, I don't 23 think we can definitively say. 24 Q. Can you cite to any papers that support 25 your understanding of that process whereby</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. Is fibrosis associated with chronic 2 inflammation? 3 A. It can be, yeah. Chronic inflammation 4 can lead to fibrosis. 5 Q. Do you know of any literature that has 6 linked talc granulomas introduced into the body 7 through the use of talc-dusted surgical gloves 8 with any sort of cancer? 9 A. So we know that talc can -- there are 10 studies that have shown talc in the ovaries, and 11 we know that chronic inflammation has been 12 implicated in cancer. 13 So if talc can reach the ovaries -- and we 14 also have evidence that talc causes chronic 15 inflammation. So if talc reaches the ovary, I 16 think it's a plausible mechanism for talc from 17 surgical gloves to cause an inflammatory reaction 18 and lead to cancer. I think that's plausible. 19 And, again, that's the plausibility arm of 20 it. You know, that's a piece of the general 21 causation opinion, but, you know, they're still 22 piecing together a lot of the etiology of ovarian 23 cancer. 24 Q. Then why -- 25 MR. KLATT: Objection, nonresponsive.</p>

<p style="text-align: right;">Page 126</p> <p>1 MS. AHERN: Nonresponsive, yeah.</p> <p>2 Q. Doctor, why are you so sure, then, that</p> <p>3 talc causes ovarian cancer?</p> <p>4 A. It's --</p> <p>5 MR. ROTMAN: Objection.</p> <p>6 A. So I can lay out to you my methodology.</p> <p>7 It's in the report. I did very in-depth,</p> <p>8 extensive review of the literature, which</p> <p>9 included the epi studies, animal studies, and</p> <p>10 biologic studies.</p> <p>11 And I think -- well, I know that the epi</p> <p>12 studies have been very consistent with the</p> <p>13 increased risk associated with talcum powder</p> <p>14 product usage -- I'm talking about talcum powder</p> <p>15 product, what's in the bottle -- and perineal</p> <p>16 talc application with ovarian cancer.</p> <p>17 And I think if you're looking at -- if you</p> <p>18 go through the methodology that I used and you're</p> <p>19 looking at the Bradford Hill analysis, which I've</p> <p>20 laid out in the report, I've come to the</p> <p>21 professional -- you know, my professional</p> <p>22 judgment is that the talcum powder products --</p> <p>23 weighing everything, that talcum powder products</p> <p>24 cause ovarian cancer.</p> <p>25 And I know -- and, interestingly, about</p>	<p style="text-align: right;">Page 128</p> <p>1 MS. AHERN: No. We're going back to</p> <p>2 this question.</p> <p>3 MR. ROTMAN: Okay. That's fine.</p> <p>4 So you're asking her again a question</p> <p>5 that she previously answered.</p> <p>6 MR. KLATT: No --</p> <p>7 MS. AHERN: I'm interested in --</p> <p>8 MR. KLATT: -- a question she didn't</p> <p>9 answer.</p> <p>10 MS. AHERN: -- the question she didn't</p> <p>11 answer first.</p> <p>12 BY MS. AHERN:</p> <p>13 Q. Which is: "Do you know of any</p> <p>14 literature that has linked talc granulomas</p> <p>15 introduced into the body through the use of</p> <p>16 talc-dusted surgical gloves with any sort of</p> <p>17 cancer?"</p> <p>18 Do you know or not know of any literature</p> <p>19 that supports that?</p> <p>20 A. Well, first of all, I think we're</p> <p>21 talking about -- you're talking about surgical</p> <p>22 glove talc, right, which is pharmaceutical-grade</p> <p>23 talc, which is different from the talcum powder</p> <p>24 product that I'm opining about.</p> <p>25 And we know that these talc particles can</p>
<p style="text-align: right;">Page 127</p> <p>1 three weeks after I wrote my report, there was</p> <p>2 the Health Canada report that, in reading their</p> <p>3 methodology and the literature that they</p> <p>4 reviewed, was very similar to what I reviewed and</p> <p>5 my methodology. And they came to the same</p> <p>6 conclusion.</p> <p>7 MR. KLATT: Objection.</p> <p>8 MS. AHERN: Objection. Nonresponsive.</p> <p>9 Q. Doctor, my question was: Do you know</p> <p>10 of any literature that has linked -- sorry.</p> <p>11 My first question we're going to go back to</p> <p>12 now is: Do you know of any literature that has</p> <p>13 linked talc granulomas introduced into the body</p> <p>14 through the use of talc-dusted surgical gloves to</p> <p>15 any sort of cancer?</p> <p>16 MR. ROTMAN: Objection.</p> <p>17 MS. AHERN: What's the objection?</p> <p>18 MR. ROTMAN: Your question was --</p> <p>19 MS. AHERN: I'm reading it.</p> <p>20 MR. ROTMAN: -- why are you so certain.</p> <p>21 MS. AHERN: Well, I just told you we're</p> <p>22 going back to this question.</p> <p>23 MR. ROTMAN: Okay. So you're asking --</p> <p>24 you're not saying that she didn't -- you're not</p> <p>25 repeating your former question?</p>	<p style="text-align: right;">Page 129</p> <p>1 get to the ovary and we know that talc can cause</p> <p>2 chronic inflammation.</p> <p>3 Q. Doctor, first question about your</p> <p>4 answer is: What makes you think that cosmetic</p> <p>5 talc used in Johnson & Johnson baby powder is not</p> <p>6 pharmaceutical-grade talc?</p> <p>7 A. I'm talking about the product, the</p> <p>8 ultimate product.</p> <p>9 Q. Johnson's baby powder; correct?</p> <p>10 A. Whatever is in the bottle.</p> <p>11 Q. You're saying that's not</p> <p>12 pharmaceutical-grade talc?</p> <p>13 A. Whatever is in the bottle.</p> <p>14 Q. Okay.</p> <p>15 A. So --</p> <p>16 Q. What is your -- what is your</p> <p>17 understanding of what pharmaceutical-grade talc</p> <p>18 is and how is that different from what's in</p> <p>19 Johnson's baby powder?</p> <p>20 A. So I didn't opine on the constituents</p> <p>21 of the talcum powder that -- the baby product --</p> <p>22 talcum powder products, the Johnson & Johnson. I</p> <p>23 saw evidence as to what's in the talcum powder</p> <p>24 products, but I didn't do my own analysis as to</p> <p>25 what is in the talcum powder products.</p>

<p style="text-align: right;">Page 130</p> <p>1 But pharmaceutical-grade talc, if we're 2 talking about talc that's used in pleurodesis, 3 for example, is going to be different than talcum 4 powder products in the bottle -- 5 Q. Okay. 6 A. -- cosmetic talcum powder products. 7 Q. So how is it different? 8 A. So, again, I didn't do my own analysis 9 as to what is in the talcum powder product, but 10 that's what I am -- that's what my general 11 causation opinion is on, is the talcum powder 12 product in the bottle, that regular perineal use 13 of that causes ovarian cancer. 14 Q. My question to you is: What do you 15 understand the difference between the talcum 16 powder products and pharmaceutical-grade talc -- 17 MR. ROTMAN: Objection. 18 Q. -- to be? 19 A. So I've seen evidence that in talcum 20 powder products, there are heavy metals. There 21 are fragrances that are added to the talcum 22 powder product that, in talc used for 23 pleurodesis, they wouldn't be adding fragrances 24 to that type of talc. 25 Q. Would -- you're not saying that talcum</p>	<p style="text-align: right;">Page 132</p> <p>1 A. Well, I think I've answered, like, to 2 me, it doesn't -- it doesn't really matter 3 what -- the difference between pharmaceutical 4 talc and talcum powder products; it's whatever is 5 in that talcum powder products -- product, 6 whatever is in the bottle that women are buying 7 off the shelf and applying to their perineum. 8 MR. KLATT: Objection. Nonresponsive. 9 MS. AHERN: Objection. Nonresponsive. 10 Q. My question was -- originally was: Do 11 you know of any literature that connects talc 12 dust of surgical gloves and any sort of cancer. 13 And then you said, "First of all, I think 14 we're talking about surgical glove talc, which is 15 a pharmaceutical-grade talc, which is different 16 from the talcum powder product that I'm opining 17 about." 18 So what I'm asking you is: What is 19 different about the talcum powder product that 20 you're -- 21 A. It's what I'm opining about. You know, 22 I haven't -- 23 Q. Right. 24 A. -- looked at the talc that's used for 25 pleurodesis, for example. It's what I'm</p>
<p style="text-align: right;">Page 131</p> <p>1 powder products that are sold to consumers have 2 been altered to add heavy metals, are you? 3 A. Well, I've seen the report of 4 Dr. Crowley that looks at heavy metals and 5 fragrances in the talc, the baby product talc 6 powder that he examined. I did not do my own 7 analysis of that. 8 Q. Does pharmaceutical-grade talcum powder 9 also have associated metals and sometimes heavy 10 metals? 11 A. I'm not sure if I've seen data as to 12 what is specifically in pharmaceutical-grade 13 talcum powder, but, again, to me, what is 14 important is the ultimate product and what is in 15 that bottle. It can -- whether it's platy talc, 16 fibrous talc, asbestos, heavy metals, fragrance 17 metals. 18 I mean, to me -- you know, I've seen 19 evidence of those things in that product, but to 20 me, what I'm looking at is the final product when 21 it comes to causing ovarian cancer. 22 Q. So what is different about that final 23 product and pharmaceutical-grade talc? What 24 specific components have been added to that that 25 affect your opinions in this case?</p>	<p style="text-align: right;">Page 133</p> <p>1 separating out. 2 I've looked at the talcum powder product 3 that women use on their perineum, what they 4 bought off the shelf. I haven't looked at 5 pharmaceutical-grade -- let me correct that -- 6 pleurodesis talc, for example. I have not looked 7 at pleurodesis talc and ovarian cancer. I have 8 not looked at any literature specifically on 9 that. It's been the talcum powder products that 10 women are buying off the shelf and using on their 11 perineum. 12 Q. So if I told you that Johnson's baby 13 powder starts out as pharmaceutical-grade talc 14 and that, beyond that, fragrance is added, would 15 it be the fragrance that you're taking issue with 16 that you believe is causally associated with the 17 development of ovarian cancer? 18 A. Again, I -- it's whatever is in that 19 bottle. It could be platy talc, fibrous talc, 20 asbestos, heavy metals, fragrance. It -- to me, 21 it's the product, whatever the product is that 22 they are using. 23 Q. And you have done a biologic 24 plausibility analysis for fragrances, for metals, 25 for asbestos, for fibrous talc, and for platy</p>

<p style="text-align: right;">Page 134</p> <p>1 talc --</p> <p>2 A. So --</p> <p>3 Q. -- each one of those constituents?</p> <p>4 A. So I have looked at evidence -- so</p> <p>5 Dr. Crowley's report, I mentioned. I've looked</p> <p>6 at Dr. Longo's report. I've looked at Hopkins</p> <p>7 and the Pier charts from their depositions. I'm</p> <p>8 aware of evidence that these heavy metals and</p> <p>9 fragrances and asbestos are in there.</p> <p>10 However, I haven't done -- what I know, I</p> <p>11 looked at the -- I've looked at some literature</p> <p>12 and I've looked at the IARC categorization of the</p> <p>13 heavy metals. I've looked at Dr. Crowley's</p> <p>14 report and I've done an extensive look at</p> <p>15 asbestos and ovarian cancer.</p> <p>16 But, ultimately, those are just pieces of</p> <p>17 biological plausibility. What I'm mainly -- what</p> <p>18 I am opining about is the ultimate product. And,</p> <p>19 again, it can be platy talc, it can be fibrous</p> <p>20 talc, it can be asbestos, it can be heavy metals.</p> <p>21 It's pieces of information that strengthen</p> <p>22 the plausibility. We know that asbestos causes</p> <p>23 ovarian cancer, that certain heavy metals are</p> <p>24 carcinogens, which the IARC categorized them as.</p> <p>25 So it's just -- it's just additional pieces of</p>	<p style="text-align: right;">Page 136</p> <p>1 consistency piece of it.</p> <p>2 Q. Can I ask you -- you can go through all</p> <p>3 of it if you want, but would you rather break it</p> <p>4 down piece by piece?</p> <p>5 MR. ROTMAN: She should answer your</p> <p>6 question.</p> <p>7 MS. AHERN: I'm not sure she's</p> <p>8 answering my question. My question was: How do</p> <p>9 you come up with causation when you don't know</p> <p>10 what the exposure is?</p> <p>11 MR. ROTMAN: I think she's answering</p> <p>12 the question.</p> <p>13 MR. TISI: That wasn't the question.</p> <p>14 The question was: Do you need to know the agent?</p> <p>15 And she said the agent is the product.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. The agent is everything in it?</p> <p>18 A. Yes, the agent is whatever is in that</p> <p>19 talcum powder product.</p> <p>20 Q. So are you basing, then, your causation</p> <p>21 conclusions on the epidemiologic literature</p> <p>22 alone?</p> <p>23 A. The epidemiologic literature is very</p> <p>24 comp- --</p> <p>25 MR. ROTMAN: She was not done with her</p>
<p style="text-align: right;">Page 135</p> <p>1 information that strengthen the biological</p> <p>2 plausibility arm of it.</p> <p>3 Q. Doctor, how do you arrive at a</p> <p>4 causation conclusion without a well-defined agent</p> <p>5 of exposure?</p> <p>6 MR. ROTMAN: Objection.</p> <p>7 Q. Do you understand what I'm asking you?</p> <p>8 How do you arrive at your causation and</p> <p>9 conclusion when you're not sure what it is about</p> <p>10 the talcum powder products that's actually</p> <p>11 biologically relevant?</p> <p>12 A. Well, I think -- well, strike that.</p> <p>13 The epi studies are looking at the product</p> <p>14 that the women are using. So that is the agent.</p> <p>15 It's the -- it's the total product. That is the</p> <p>16 agent.</p> <p>17 So when you're looking through -- let me</p> <p>18 just -- so let's keep in mind that we're looking</p> <p>19 at that product.</p> <p>20 And then if you go through my Bradford Hill</p> <p>21 analysis, you look at strength of association.</p> <p>22 And, overall, there's a consistent relative risk</p> <p>23 that's between 1 and 2. I would say it's, across</p> <p>24 studies, averaging 1.3 to 1.4 relative risk, and</p> <p>25 that's consistent across studies. That's the</p>	<p style="text-align: right;">Page 137</p> <p>1 earlier answer. Now you've gone two more beyond</p> <p>2 it.</p> <p>3 MS. AHERN: She's answering. Why don't</p> <p>4 you let her answer. If she wants to go back, she</p> <p>5 can.</p> <p>6 MR. ROTMAN: No, I want her to go back.</p> <p>7 She was -- she was in the middle of going through</p> <p>8 her Bradford Hill to answer your earlier question</p> <p>9 and you cut her off. So she had covered strength</p> <p>10 of association.</p> <p>11 BY MS. AHERN:</p> <p>12 Q. Doctor, you can answer the question the</p> <p>13 way you want to answer the question.</p> <p>14 MR. ROTMAN: Now there's no question in</p> <p>15 front of her.</p> <p>16 MS. AHERN: Well, because you</p> <p>17 interrupted it.</p> <p>18 MR. ROTMAN: Let's go back to what the</p> <p>19 question was before you cut her off. "Do you</p> <p>20 understand what I'm asking you? How do you</p> <p>21 arrive at your causation and conclusion when</p> <p>22 you're not sure what it is about the talcum</p> <p>23 powder products that actually biologically --</p> <p>24 that are biologically relevant?"</p> <p>25 And then you gave -- then you started</p>

<p style="text-align: right;">Page 138</p> <p>1 an answer about the epi studies are looking at 2 the product that the women are using, and you 3 were talking about strength of association and 4 then you said, "And that's consistent across 5 studies. That's the consistency piece of it," 6 and then you were interrupted. 7 So were you done with your answer to 8 that earlier question? 9 THE WITNESS: I can continue, because I 10 think it's important. 11 I mean, I was -- my general causation 12 opinion, the methodology I used was to answer the 13 question: Does perineal application of talcum 14 powder products, the, you know, baby powder 15 product that you buy off the shelf, does that 16 cause ovarian cancer? So it's whatever is in 17 that bottle. 18 So with the methodology that I used, 19 looking at the epi data, but also considering the 20 Bradford Hill criteria -- which, you know, 21 looking for specificity is another one. So most 22 of the studies showed a stronger -- a strong 23 association with serous ovarian cancer, but it 24 was basically associated with epithelial ovarian 25 cancer, so all groups of epithelial ovarian</p>	<p style="text-align: right;">Page 140</p> <p>1 generally accepted knowledge of the disease in 2 question. 3 So we know that particles can reach the 4 ovary. We know that talc can cause chronic 5 inflammation. We know that chronic inflammation 6 is associated with certain types of cancer. We 7 know that certain types of ovarian cancer have 8 shown association with chronic inflammatory 9 conditions. 10 So, again, going through all this is 11 experiment and analogy, experiment with the 12 animal studies and the in vitro studies. And 13 analogy, I used the example of asbestos, because 14 even though asbestos is -- you know, asbestos is 15 chemically similar, you can have asbestos fibers 16 and talc fibers, but it's a similar mineral 17 chemically, and we know that that is a 18 carcinogen. So that's part of the analogy. 19 But, again, it's the whole picture. I 20 mean, you look at the -- all of this data 21 following my methodology and you apply the 22 Bradford Hill criteria guidelines -- the Bradford 23 Hill guidelines. And, looking at all that, my 24 professional judgment is that the talcum powder 25 products can cause ovarian cancer.</p>
<p style="text-align: right;">Page 139</p> <p>1 cancer. It was pretty specific, the epi data, 2 for that type of ovarian cancer. 3 Temporality. If you look at that, I 4 mean, the case-control studies are retrospective 5 reviews, so we know that they were using talc 6 before their diagnosis of ovarian cancer. 7 Biological gradient. For those studies 8 that looked at a biological gradient, there was 9 an evident -- there was evidence of a 10 dose-response, not all of the times statistically 11 significant, but the trend -- you can see a trend 12 of a dose-response across studies. 13 And then we get into the plausibility 14 piece, which you've been discussing mostly so far 15 in this deposition, which has to do with the 16 plausible mechanism of talcum powder -- what I'm 17 thinking of, talcum powder products -- whatever 18 is in that bottle was what I'm looking at -- 19 talcum powder products causing -- the 20 plausibility of it causing a chronic inflammatory 21 response, leading to ovarian cancer. We've been 22 discussing that quite a bit today. 23 And then coherence. So I can refer 24 again to my report. Coherence, in this context, 25 means coherence between epidemiologic and</p>	<p style="text-align: right;">Page 141</p> <p>1 Q. Okay. Are you done? I don't want to 2 interrupt you. 3 A. I think I answered the question. 4 Q. Okay. One of the things, and I guess a 5 major component of the talcum powder products, 6 would be talc; correct? 7 A. Presumably -- it's called talcum 8 powder, so presumably, talc would be a 9 constituent. 10 Q. Do you know what percentage of talcum 11 powder products is talc? 12 A. Again, I did not do my own analysis as 13 to how much talc was in that product. 14 Q. Do you know whether any of the heavy 15 metals that you looked at or were examined by 16 other experts in this litigation, whether any of 17 those are known carcinogens for the ovary? 18 A. So it's another piece of information. 19 There is not, to my knowledge -- looking at what 20 the IARC looked at, there's not data right now on 21 those heavy metals and ovarian cancer, but 22 it's -- it's a -- it's a piece of the puzzle. 23 It's a piece of information. 24 The IARC has called some of them 25 carcinogenic, some of them probably carcinogenic,</p>

<p style="text-align: right;">Page 142</p> <p>1 so we know that they can cause cancer. And if 2 they're in the talcum powder products, then it's 3 just another piece to the puzzle of plausibility. 4 Q. Are you saying that the probably 5 carcinogenic category for IARC means that they 6 can cause cancer? 7 A. Well, we can look at what the IARC 2A 8 categorization -- category actually says, what 9 they break it down. But my understanding is 10 it's -- probably carcinogenic means it probably 11 causes cancer, more likely than not, probably 12 causes cancer. 13 Q. How many categories does IARC have? 14 A. They have four. 15 Q. What is the -- what is Category 1? 16 A. Carcinogenic. 17 Q. Known to be carcinogenic? 18 A. Mm-hmm. 19 Q. And then the next? 20 A. Probably carcinogenic. 21 Q. And then? 22 A. Possibly carcinogenic. 23 Q. And then? 24 A. I think it's unclassifiable. I have to 25 look. But I think it's uncertain, basically.</p>	<p style="text-align: right;">Page 144</p> <p>1 little too wide a net. I think science is always 2 evolving and there's always the possibility of an 3 unknown cause of a certain type of cancer. 4 MS. AHERN: Objection. Nonresponsive. 5 Q. My question was just: Can carcinogens 6 be organ specific? 7 A. And I feel like I answered that fairly. 8 Q. Do you know of carcinogens that are 9 organ specific? 10 A. I know -- for example, we know that H. 11 Pylori causes increased risk of gastric cancer, 12 but not oral or esophageal cancer. 13 We know that HPV infection can cause 14 cervical cancer, anal cancer, certain types of 15 squamous cell carcinomas of the oropharyngeal 16 system, but not, you know, of the endometrium, 17 for example. 18 So we know that certain things cause certain 19 cancers and aren't -- haven't been associated 20 with other types of cancers. But to cast that 21 wide a net, to say that a carcinogen is only 22 going to cause one type of cancer or this cancer 23 is caused only by this carcinogen, I think that's 24 too wide a net, because I feel like research is 25 constantly evolving. We're constantly learning</p>
<p style="text-align: right;">Page 143</p> <p>1 Q. And then what is the last? 2 A. And then known not to be carcinogenic. 3 Q. How many agents are in the known not to 4 be carcinogenic category? 5 A. Very, very few. 6 Q. One; right? 7 A. That's plausible. I haven't looked at 8 the list recently. 9 Q. So going back to the major component, 10 you don't know what percentage of talcum powder 11 products are actually talc? 12 MR. ROTMAN: Objection. 13 A. I have not done my own analysis as to 14 what the components are of that talcum powder -- 15 of the talcum powder products. 16 Q. Do you agree that carcinogens can be 17 organ specific? 18 A. I will agree that certain tissues 19 respond to certain things differently. 20 Q. Do you agree that carcinogens can be 21 organ specific? 22 A. Certain tissues respond to certain 23 things differently. If you're casting that wide 24 a net to say that one specific carcinogen only 25 causes one type of cancer, I think that's a</p>	<p style="text-align: right;">Page 145</p> <p>1 of new causal factors in cancer. 2 Q. Do you think that dose is an important 3 consideration when you're looking at the 4 toxicologic effects of an agent on a tissue? 5 A. I think it is a piece of information. 6 I'm looking at my biological gradient portion of 7 my report, and I said in my report that it was an 8 important factor in my analysis because it does 9 add information to the overall causality. 10 Q. Are there agents that can be toxic at 11 certain levels and not toxic at other levels? 12 A. There are certainly agents that are 13 more toxic with increased exposure and increased 14 duration. We don't know all of the thresholds 15 for carcinogenicity of all carcinogens. 16 Q. As part of the biologic plausibility 17 analysis that you would do on a particular agent, 18 would that take into consideration the relative 19 levels of exposure that a person would have to 20 that agent? 21 A. Well, dose-response -- I -- I'm taking 22 it -- your question -- can you rephrase the 23 question? I'm sorry. I just want to make sure 24 I'm answering it accurately. 25 Q. To determine whether it's biologically</p>

<p style="text-align: right;">Page 146</p> <p>1 plausible for a particular agent to cause a 2 particular harm, would you need to be able to 3 characterize the dose of that agent that is 4 required to elicit the effect that you're looking 5 for?</p> <p>6 A. I think it's a piece of the 7 information -- a piece of information, but you're 8 not always going to be able to determine a 9 dose-response. It's going to depend on the 10 carcinogen, the agent, the routes of exposure. 11 You're just not always going to have that data, 12 unfortunately. It would be nice to have, but 13 you're not always going to have it, and you don't 14 necessarily have to have it to come to 15 plausibility.</p> <p>16 Q. And do you have well-characterized 17 levels of exposure to the ovaries for women who 18 are using talc perineally?</p> <p>19 MR. ROTMAN: Objection.</p> <p>20 A. So some of the -- we're never really 21 going to be able to figure out what an actual -- 22 to characterize what an actual dose -- dose of 23 talcum powder product of what -- of a talcum 24 powder product in a particular use. We don't 25 know how much a woman is putting on her hand to</p>	<p style="text-align: right;">Page 148</p> <p>1 and ovarian cancer. I certainly saw some of the 2 data about talc migration and cornstarch on 3 surgical gloves migration, but I didn't 4 specifically -- I don't know if -- I don't even 5 know if that study has really been done.</p> <p>6 Q. Did you consider the publications on 7 talc responses -- or, excuse me, did you consider 8 the publications on granulomatous reactions to 9 talc from surgical gloves to be relevant to your 10 biologic plausibility analysis?</p> <p>11 A. It's a piece of information that 12 talc -- now, again, surgical glove talc, for me, 13 is different than the talcum powder products.</p> <p>14 You know, my general causation opinion -- I 15 just want to be clear -- is about, you know, 16 talcum powder products, not the talc used in 17 pleurodesis, not talc on surgical gloves.</p> <p>18 Having said that, I think it's an important 19 piece of information to know that talc on 20 surgical gloves can cause a granulomatous 21 reaction, because that is further evidence for 22 plausibility that talcum powder products -- 23 they're called talcum powder products, so, again, 24 it's sort of an assumption. It doesn't really 25 matter to me what's in there, but my assumption</p>
<p style="text-align: right;">Page 147</p> <p>1 place into the perineum. We don't know how much 2 of that product is getting to the ovary. We know 3 that it can get to the ovary because we've seen 4 talc in the ovary. But where -- it's extremely 5 difficult in this type of situation, when women 6 use the product differently, to know what the 7 dose -- what a single dose is.</p> <p>8 Now, if you're talking long-term, frequent 9 use of talcum powder products, of course, the 10 exposure is going to be greater than a single use 11 of that product.</p> <p>12 But are we ever going to know what one dose 13 of talcum powder product is? I don't think we're 14 going to be able to say that and how much of one 15 dose reaches the ovary.</p> <p>16 But, certainly, again, with -- over time, 17 increased frequency and duration, it's -- you 18 know, more of that product is going to reach the 19 ovary.</p> <p>20 Q. So going back to the discussion we had 21 earlier about surgical glove talc, do you know of 22 any literature that links exposure to talcum 23 powder -- pharmaceutical-grade talcum powder from 24 surgical gloves to any kind of cancer?</p> <p>25 A. I did not opine on surgical glove talc</p>	<p style="text-align: right;">Page 149</p> <p>1 is that whatever -- the talc or whatever is in 2 that product is causing the -- a chronic 3 inflammation. And so it's part -- it's a piece 4 of evidence for the plausibility.</p> <p>5 Q. So are you not aware of any studies, 6 based on the review that you did conduct, that 7 link surgical glove talcum powder with the 8 development of any cancer?</p> <p>9 MR. ROTMAN: Objection.</p> <p>10 A. So I'm not sure how you could do that. 11 If you're looking at patients who -- I think that 12 would be a very difficult study to design.</p> <p>13 If you're looking at women -- if you're 14 doing a case-control study -- I'm just 15 thinking -- and you're looking at patients who 16 have been diagnosed with ovarian cancer who have, 17 at any time, had surgery during the time period 18 that talc was used on surgical gloves, I think 19 that would be a difficult study.</p> <p>20 Q. My question to you was --</p> <p>21 MR. KLATT: Objection. Nonresponsive.</p> <p>22 Q. My question to you was: Are you aware 23 of any studies or literature that link 24 talc-dusted surgical gloves to the development of 25 any kind of cancer?</p>

<p style="text-align: right;">Page 150</p> <p>1 MR. ROTMAN: Objection.</p> <p>2 THE WITNESS: My thing is not --</p> <p>3 MR. ROTMAN: There's a button you can</p> <p>4 push.</p> <p>5 THE WITNESS: Oh, "follow."</p> <p>6 MR. ROTMAN: Do you see the button</p> <p>7 that's flashing on the right-hand --</p> <p>8 THE WITNESS: Yeah.</p> <p>9 MR. ROTMAN: -- side? If you hit that,</p> <p>10 it should go to the bottom.</p> <p>11 THE WITNESS: Okay. I see. Yup.</p> <p>12 MS. AHERN: And I'll withdraw that,</p> <p>13 because there's -- the question asked first was,</p> <p>14 I think, better. I slightly modified it on</p> <p>15 accident.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. Are you aware of any studies, based on</p> <p>18 your review, that link surgical glove talcum</p> <p>19 powder with the development of any kind of</p> <p>20 cancer?</p> <p>21 And, Doctor, to be clear, I'm only</p> <p>22 interested in whether you know of a study, not</p> <p>23 whether one could be conducted.</p> <p>24 A. Off the top of my head, it's possible</p> <p>25 that one exists, but I can't come up with one off</p>	<p style="text-align: right;">Page 152</p> <p>1 could be helpful information to my general</p> <p>2 causation opinion. So it's possible that I did.</p> <p>3 Q. Is it in your report or cited in any of</p> <p>4 your reference lists?</p> <p>5 A. Again, I can look through my whole</p> <p>6 reference list. It's the same answer. Off the</p> <p>7 top of my head, I don't know the answer to that.</p> <p>8 Q. Do you know of any studies or any data</p> <p>9 that link foreign-body granulomas to the</p> <p>10 development of any kind of cancer?</p> <p>11 A. Well, we know that asbestos can cause a</p> <p>12 granulomatous reaction and asbestos is certainly</p> <p>13 associated with mesothelioma and lung cancer.</p> <p>14 Q. Are there other biologic properties of</p> <p>15 asbestos that contribute to its carcinogenicity?</p> <p>16 A. It can provoke a reactive oxygen</p> <p>17 species inflammatory response.</p> <p>18 Q. Can it disrupt DNA?</p> <p>19 A. It can based on that mechanism, yes.</p> <p>20 Q. Have you seen any studies or data</p> <p>21 suggesting that talcum powder can do those</p> <p>22 things?</p> <p>23 A. I've seen studies that show that talcum</p> <p>24 powder can increase production of reactive oxygen</p> <p>25 species and can change gene expression in</p>
<p style="text-align: right;">Page 151</p> <p>1 the top of my head.</p> <p>2 Q. Do you know of any data linking</p> <p>3 surgical glove talcum powder with the development</p> <p>4 of any cancer?</p> <p>5 MR. ROTMAN: Objection.</p> <p>6 A. It would be my same answer.</p> <p>7 Q. That you don't know, but there might</p> <p>8 be?</p> <p>9 A. Sitting here right now, I can't come up</p> <p>10 with a specific study that evaluated ovarian</p> <p>11 cancer patients who have had surgery with talcum</p> <p>12 powder gloves.</p> <p>13 Q. Any cancer. Not ovarian cancer, any</p> <p>14 cancer.</p> <p>15 A. Similar. Sitting here right now, I</p> <p>16 cannot think of one off the top of my head.</p> <p>17 Q. And wouldn't that have been something</p> <p>18 you think you would have picked up in your</p> <p>19 review?</p> <p>20 A. It's possible that I did. I just said</p> <p>21 I can't think of it off the top of my head. It's</p> <p>22 possible that I did at some point.</p> <p>23 But my -- and, again, I tried to make every</p> <p>24 effort to be able to identify studies and</p> <p>25 literature and evidence that were relevant or</p>	<p style="text-align: right;">Page 153</p> <p>1 mesothelial cells. So, yes, I mean -- let me go</p> <p>2 back to your question.</p> <p>3 So I would say, yes, there are studies that</p> <p>4 show talc can cause the production of reactive</p> <p>5 oxygen species and reactive nitrogen species,</p> <p>6 which can disrupt DNA, similar to asbestos.</p> <p>7 Q. How do reactive oxygen and nitrogen</p> <p>8 species disrupt DNA similar to asbestos?</p> <p>9 A. Well, it's the reactive oxygen species</p> <p>10 -- it's part of this feedback loop with -- what's</p> <p>11 the word I'm looking for? -- tumor factors like</p> <p>12 COX and TNF alpha. It's related to those types</p> <p>13 of expressions and an inflammatory response.</p> <p>14 Q. Are you relying on cell studies?</p> <p>15 MR. ROTMAN: Objection.</p> <p>16 A. I have looked at cell studies. The</p> <p>17 Buz'Zard study is one, and I know Saed has done a</p> <p>18 lot with myeloperoxidase and ovarian cells. He</p> <p>19 recently came out with a paper.</p> <p>20 So it's, again, a piece of information</p> <p>21 towards the plausibility arm of my general</p> <p>22 causation opinion.</p> <p>23 Q. Have you seen any studies in animals or</p> <p>24 in humans that have linked the specific enzymes</p> <p>25 that Dr. Saed has evaluated in cell studies to</p>

<p style="text-align: right;">Page 154</p> <p>1 the development of ovarian cancer?</p> <p>2 A. So there have been some studies that</p> <p>3 have looked at anti-inflammatory drugs, aspirin</p> <p>4 and NSAIDs in particular.</p> <p>5 The data on NSAIDs has been less consistent,</p> <p>6 but the data on aspirin has been consistent, in</p> <p>7 that it lowers the risk of ovarian cancer with</p> <p>8 regular aspirin use.</p> <p>9 And aspirin, one of the mechanisms of action</p> <p>10 is on the cyclooxygenase expression, which is</p> <p>11 similar to the cyclooxygenase expression seen in</p> <p>12 some of the in vitro studies.</p> <p>13 Q. So my question was: Have you seen any</p> <p>14 studies in animals or in humans that have linked</p> <p>15 specific enzymes that Dr. Saed has evaluated in</p> <p>16 his cell studies to the development of ovarian</p> <p>17 cancer?</p> <p>18 MR. ROTMAN: Objection.</p> <p>19 Q. Are you relying, then, on epidemiologic</p> <p>20 studies looking at NSAID and aspirin use?</p> <p>21 MR. ROTMAN: Objection.</p> <p>22 A. I'm saying that the NSAID and aspirin</p> <p>23 use is another piece of information that -- as to</p> <p>24 plausibility, mechanism -- and mechanism of</p> <p>25 regulation of pathways that can result in</p>	<p style="text-align: right;">Page 156</p> <p>1 get it.</p> <p>2 THE WITNESS: Oh, I'm sorry.</p> <p>3 A. "Ovarian cancer may be analogous,</p> <p>4 therefore, to plural mesothelioma, which has been</p> <p>5 shown to be caused by asbestos, a chemical</p> <p>6 similar to talc."</p> <p>7 Q. Is that the complete passage that</p> <p>8 you're looking at?</p> <p>9 A. I believe that is why I had highlighted</p> <p>10 that one, yes.</p> <p>11 Q. You'd agree that this version of</p> <p>12 Blaustein's textbook was published in 1994?</p> <p>13 A. Yes, I am aware.</p> <p>14 Q. Would you agree that a number of the</p> <p>15 risk factors that have been identified here,</p> <p>16 there have been additional studies published on?</p> <p>17 A. Yes.</p> <p>18 Q. Would you agree that alcohol is a known</p> <p>19 risk factor these days for ovarian cancer?</p> <p>20 A. I don't think that's been borne out to</p> <p>21 be the case. But with talc, there's continued to</p> <p>22 be several case controls and meta-analyses which</p> <p>23 have continued to be consistent with the</p> <p>24 increased risk of ovarian cancer cited in the</p> <p>25 studies that were cited here, which I didn't</p>
<p style="text-align: right;">Page 155</p> <p>1 reactive oxygen species and cause an inflammatory</p> <p>2 response.</p> <p>3 MR. KLATT: Objection. Nonresponsive.</p> <p>4 MS. AHERN: Same.</p> <p>5 Q. Let's go back to that. We'll finish up</p> <p>6 this Exhibit 11.</p> <p>7 What was the next page, if any, the last</p> <p>8 page in your photocopy?</p> <p>9 A. Okay. So this is Page 1216 of the</p> <p>10 fourth edition, if I am correct. Give me one</p> <p>11 second while I find it.</p> <p>12 Okay. So the reason why Page 1216 is there</p> <p>13 is because it starts the section on ovarian</p> <p>14 cancer, which then continues on to Page 1217.</p> <p>15 And it says -- the last paragraph on Page 1217</p> <p>16 says, "Other suggested factors affecting ovarian</p> <p>17 cancer risk include talc exposure, a history of</p> <p>18 mumps infection, and alcohol consumption. Talc</p> <p>19 exposure, which has been related to an excess</p> <p>20 risk of ovarian cancer in a number of</p> <p>21 case-control studies, is of interest biologically</p> <p>22 in that ovarian cancer is thought to arise from</p> <p>23 the mesothelium that lines the peritoneal</p> <p>24 cavity."</p> <p>25 MR. ROTMAN: Slow it down so she can</p>	<p style="text-align: right;">Page 157</p> <p>1 actually Xerox. You have the book, so --</p> <p>2 Yes, I agree this was 1994, but taken into</p> <p>3 context of the subsequent studies and literature</p> <p>4 looking at talc and ovarian cancer, I think it's</p> <p>5 still relevant.</p> <p>6 Q. Have there been a number of updates and</p> <p>7 changes to the classification of tumors since</p> <p>8 1994?</p> <p>9 A. Since 1994, sort of semantically. We</p> <p>10 still have the same subtypes of ovarian cancer.</p> <p>11 There's been a new categorization. We talked</p> <p>12 about the Type 1 and Type 2 ovarian cancers.</p> <p>13 So not a complete overhaul in</p> <p>14 categorization; I think just different ways to</p> <p>15 category the same entities, let's --</p> <p>16 Q. Has the --</p> <p>17 A. -- put it that way.</p> <p>18 Q. Sorry.</p> <p>19 Has the understanding of the origin of</p> <p>20 ovarian tumors evolved significantly since 1994?</p> <p>21 A. So this mentions -- we talked about</p> <p>22 this a little bit earlier -- this does mention</p> <p>23 that at this time, in 1994, there was thought</p> <p>24 that ovarian cancer might arise from the</p> <p>25 mesothelium. So the ovary is covered by a layer</p>

<p style="text-align: right;">Page 158</p> <p>1 of mesothelium. That's the outer layer. And so 2 in 1994, that was still, I would say -- this is 3 before my residency, a little before my time -- 4 that that was the most common thought, that 5 that's where the ovarian cancer -- cancers are 6 arising from. Now, since then we've discussed 7 some of the other more recent findings of the 8 etiology.</p> <p>9 But, anyway, I just -- I had read this a 10 couple of days ago and, you know, it was -- it 11 was a reference that I think is still relevant 12 because of the -- the subsequent case controls 13 and meta-analyses that were done since then that 14 I think still make it relevant, although, again, 15 I -- we're not -- we're still not absolutely sure 16 where all of these ovarian epithelial tumors are 17 arising from. But we have a little more evidence 18 than we did in 1994.</p> <p>19 Q. And in 1994, the first prospective 20 cohort study had not yet been published; correct?</p> <p>21 A. I believe that is correct.</p> <p>22 Q. So we would be -- these numbers here 23 in -- that are discussed for talc exposure would 24 be, essentially, just the retrospective case 25 controls that had been published up to that point</p>	<p style="text-align: right;">Page 160</p> <p>1 page just because it was a continuation of that. 2 So, yes, I think we're done with the fourth 3 edition.</p> <p>4 Sorry. I'm starting to talk fast because 5 I'm excited for lunch.</p> <p>6 MS. AHERN: We can take a break for 7 lunch, then.</p> <p>8 THE VIDEOGRAPHER: Here ends Media 3. 9 Off the record, 1:05 p.m. 10 (Lunch recess was taken.) 11 ("Blaustein's Pathology of the 12 Female Genital Tract," Fifth Edition, 13 marked Exhibit 12.) 14 (Excerpt of Blaustein's 15 Pathology of the Female Genital Tract," 16 Fifth Edition marked Exhibit 13.)</p> <p>17 THE VIDEOGRAPHER: Here begins Media 18 No. 4 in today's deposition of Sarah Kane, M.D. 19 Back on the record, 1:45 p.m.</p> <p>20 BY MS. AHERN: 21 Q. Okay. Hi, Dr. Kane. 22 A. Hello. 23 Q. I'm looking here at Blaustein's 24 Pathology of the Female Genital Tract, Fifth 25 Edition, which you brought with you here today.</p>
<p style="text-align: right;">Page 159</p> <p>1 or the specific ones -- 2 A. Yeah. You have the reference list of 3 the reference numbers 47, 69, 70, and 182.</p> <p>4 Q. Cramer? You said 59? 5 A. 69. 6 Q. Harlow, 92. 7 A. 70. 8 Q. 70. Hartge. 9 And 83. 10 A. And 182. 11 Q. And Whittemore, 1988. 12 A. So, yes, that was before. They only 13 looked up until 1988.</p> <p>14 Q. Okay.</p> <p>15 MR. ROTMAN: Hunter, a good time to 16 take our lunch break? It's been an hour since 17 our last -- since we started.</p> <p>18 MS. AHERN: Sure. I'm sure people 19 could use a bio break too.</p> <p>20 Q. Are these the only pages that you 21 photocopied from this book -- or in -- sorry. 22 Let me rephrase that.</p> <p>23 Have we finished with the photocopy of 24 Exhibit 11 or are there more pages? 25 A. I think -- I think I Xeroxed this last</p>	<p style="text-align: right;">Page 161</p> <p>1 I marked it as Exhibit 12 to your deposition. 2 You can have it back.</p> <p>3 A. Okay.</p> <p>4 Q. Thank you. And inside, you brought 5 with you a photocopy of the cover page and also 6 Page 629. I'll hand that back to you. I think 7 there's only one copy. I've marked that as 8 Exhibit 13.</p> <p>9 A. Oh, okay. 10 Q. Here you go. 11 A. Okay.</p> <p>12 MR. TISI: What was the page? I'm 13 sorry.</p> <p>14 THE WITNESS: 629. Do you want the 15 textbook back?</p> <p>16 Q. Whichever one you'd rather actually 17 pass back to me. Thank you.</p> <p>18 Can you tell us, on Page 629, what 19 information you thought was relevant to your 20 review of the talc issue?</p> <p>21 A. Yes. I believe this is under "Foreign 22 Body." So this is diseases of the fallopian 23 tube. So under "Foreign Body" -- hold on one 24 second. Okay. It says, "Foreign material may be 25 introduced into the tube in the course of</p>

<p style="text-align: right;">Page 162</p> <p>1 gynecologic investigation, especially 2 hysteroscopic -- I can't say the word, 3 hysterosalpingo -- anyway, HPG, lubricant jelly, 4 mineral oil and starch and talc powder may cause 5 a lipoid or granulomatous salpingitis. An 6 intense phagocytic reaction to introduce lipid 7 material causes" -- 8 THE COURT REPORTER: Excuse me. 9 A. Sorry. I think that's basically the -- 10 that is the end. 11 No. At the very end of the page, it says, 12 "Talc may cause mucosal or serosal granulomas. 13 Examination of all granulomas or foreign body 14 reactions under polarized light is useful in the 15 recognition of these processes. Other disease 16 processes in the tube such as leprosy or 17 amyloidosis are so infrequent that they are of 18 little clinical or pathologic significance." 19 Q. How does that information inform your 20 opinions today? 21 A. So it's just another -- again, similar 22 to the other things that we reviewed in the other 23 edition, just another piece of evidence that talc 24 causes mucosal and serosal granulomas, and 25 they're talking about the fallopian tube in this</p>	<p style="text-align: right;">Page 164</p> <p>1 experimental studies or animal studies 2 linking talc foreign-body responses to 3 development of cancer? 4 A. From what I can recall in those 5 textbooks, I don't think they went into any more 6 detail than what I've read for you. 7 Q. Okay. What else did you bring with you 8 today? Anything that we haven't covered other 9 than the boxes behind me? 10 A. Correct. I don't think so. Mr. Rotman 11 brought a copy of my report, but that is all. 12 This -- let me look. 13 All of these have been marked already. 14 Yeah. 15 Q. All right. Doctor, you've got a copy, 16 but I'm going to hand you another one. I've 17 marked as Exhibit 14 a copy of your expert report 18 dated November 15, 2018. 19 (Rule 26 Expert Report of Sarah 20 E. Kane, M.D. marked Exhibit 14.) 21 Q. Can you review Exhibit 14 and tell us 22 if this is indeed your expert report dated 23 November 15, 2018? 24 A. Yes. This appears to be my report. 25 Q. And you brought with you earlier an</p>
<p style="text-align: right;">Page 163</p> <p>1 chapter. 2 MR. KLATT: Can I interrupt? 3 (Discussion off the record.) 4 MR. LOCKE: I'm on right now. Thanks, 5 Mike. 6 BY MS. AHERN: 7 Q. And, Doctor, did you review any other 8 sections of Exhibit 12, Blaustein, Fifth Edition? 9 A. I believe I did. I think in this 10 edition, from what I recall, that was the -- the 11 reference was in the fallopian tube. 12 Q. Is that what we just discussed on 13 Page 629? 14 A. Yes. 629 was where talc was discussed 15 in the fallopian tube. 16 Q. Did you see any other information in 17 any of the Blaustein texts that we reviewed today 18 that suggests that foreign body granulomas caused 19 by talc have been associated with the development 20 of ovarian cancer? 21 A. Well, we saw mention of the 22 epidemiologic studies in the fourth edition that 23 we reviewed. 24 Q. So other than the epidemiology, is 25 there any reference to pathology studies or</p>	<p style="text-align: right;">Page 165</p> <p>1 updated copy of your CV; correct? 2 A. Yes, I did. 3 Q. Which we marked Exhibit 2. 4 (Document entitled "References 5 Cited and Other Material and Data 6 Considered" marked Exhibit 15.) 7 BY MS. AHERN: 8 Q. And Exhibit B to your report was 9 entitled "References Cited and Other Material and 10 Data Considered." I've marked that as Exhibit 15 11 to your deposition. 12 A. Okay. 13 Q. Okay. And Exhibit 15 isn't paginated 14 but consists of 11 pages. The first ten pages of 15 materials consist of 186 items identified by the 16 caption on the top of Page 1 as "Literature"; is 17 that correct? 18 A. I'm sorry. Are you talking about the 19 "References Cited and Other Material and Data 20 Considered," Exhibit 15? 21 Q. Yes. 22 A. Yes. There is a list of 186 literature 23 references. 24 Q. And the materials listed on Page 11 are 25 identified by a caption as "Other Sources" and</p>

<p style="text-align: right;">Page 166</p> <p>1 include an additional 17 items; is that correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. So did you prepare Exhibit 15?</p> <p>4 A. Yes. I did.</p> <p>5 Q. Did you type this out yourself?</p> <p>6 A. I did. Yes.</p> <p>7 Q. Okay. And how did you go about pulling</p> <p>8 this together?</p> <p>9 A. I'm -- in what way?</p> <p>10 Q. Did you keep a running list of the</p> <p>11 citations as you went and then pull this all</p> <p>12 together at the end of your report?</p> <p>13 A. Yes. So what happened is this was my</p> <p>14 first medical expert witness report I have</p> <p>15 written. And you'll notice that -- let's see,</p> <p>16 all of the -- oh, I'm sorry. This doesn't</p> <p>17 include the January 4th list; right?</p> <p>18 Q. We'll get there.</p> <p>19 A. Okay. So that's what I kind of want to</p> <p>20 explain. What happened is, the reason why you</p> <p>21 had a January 4th list, is because I wrote</p> <p>22 this -- the accepted form for published</p> <p>23 literature is listing literature that you've</p> <p>24 actually cited within the body of your report,</p> <p>25 and so it was my misunderstanding. I was not</p>	<p style="text-align: right;">Page 168</p> <p>1 that you -- the list that you got yesterday is</p> <p>2 stuff that I had reviewed, I believe. I have to</p> <p>3 look at it.</p> <p>4 But my point is that list that you got</p> <p>5 yesterday was varied, and -- when I looked at it,</p> <p>6 and it was just an effort to be as complete as</p> <p>7 possible.</p> <p>8 Q. Okay. And just looking -- we'll get</p> <p>9 there, but just looking at Exhibit 15, which --</p> <p>10 the first ten pages, which are the references?</p> <p>11 A. Mm-hmm.</p> <p>12 Q. So do you define the references as the</p> <p>13 specific sources that you cited within the body</p> <p>14 of your report?</p> <p>15 A. These are sources that I cited within</p> <p>16 the body of my report.</p> <p>17 Q. And are these the sources that you rely</p> <p>18 on to support the opinions expressed in your</p> <p>19 report?</p> <p>20 A. So these are some of the references</p> <p>21 that I used. Again, I also had reviewed the</p> <p>22 subsequent -- the literature and the other data</p> <p>23 in the subsequent lists. So I would not say this</p> <p>24 is all-encompassing, but ultimately, with all the</p> <p>25 lists you have now, I'm hoping that that is</p>
<p style="text-align: right;">Page 167</p> <p>1 aware at first that you guys were going to want a</p> <p>2 list of everything that I had reviewed.</p> <p>3 So what I tried to do is this, I think, was</p> <p>4 turned in at the same time, so Exhibit 15 was</p> <p>5 turned in at the same time as Exhibit 14, and it</p> <p>6 has the literature that was cited within the body</p> <p>7 of the report.</p> <p>8 And then when I realized I needed to get a</p> <p>9 list together of everything, as complete a list</p> <p>10 of everything that I thought I reviewed, I put</p> <p>11 together the January 4th list, which was -- I had</p> <p>12 to sort of recreate -- and I kept almost all of</p> <p>13 those -- all of this literature in different</p> <p>14 files.</p> <p>15 I had to do a little bit of recreation</p> <p>16 because, as I mentioned before, I lost a couple</p> <p>17 of hard drives during this whole process, which</p> <p>18 was not fun. But thankfully, I was -- I had</p> <p>19 backed up a lot of it.</p> <p>20 So I tried to be as complete as possible.</p> <p>21 It is possible that there are a few things I</p> <p>22 reviewed that did not make the list, which I</p> <p>23 think I realized on the list that you got</p> <p>24 yesterday there might have been a couple that I</p> <p>25 had reviewed before, but most of that literature</p>	<p style="text-align: right;">Page 169</p> <p>1 encompassing of at least all of the stuff that I</p> <p>2 considered. I wouldn't necessarily say "rely</p> <p>3 on," but at least everything that I considered.</p> <p>4 Q. Okay. And that was -- my next question</p> <p>5 was: Do you differentiate between the sources</p> <p>6 cited here as references and those that you just</p> <p>7 considered but weren't included as references?</p> <p>8 A. Not necessarily. These are the ones</p> <p>9 that ended up getting cited in the report. Now,</p> <p>10 there were different drafts, which at one point</p> <p>11 some of the other ones were cited, and there was</p> <p>12 a little bit of changing it around, which there's</p> <p>13 a couple -- I think there are a couple of</p> <p>14 typographical-type errors in a couple of the</p> <p>15 references because of that.</p> <p>16 But essentially, there isn't that much of a</p> <p>17 difference, I would say, except to say that this</p> <p>18 is the literature that I ended up specifically</p> <p>19 citing.</p> <p>20 But all of the literature that I looked at,</p> <p>21 I considered.</p> <p>22 Q. Would you say that all of the</p> <p>23 literature that you looked at, which would</p> <p>24 include your other sources here on Exhibit 15,</p> <p>25 your January 4, 2018, reference list, and the</p>

<p style="text-align: right;">Page 170</p> <p>1 ones served yesterday, January 24th, would you 2 say that you relied on all of those materials? 3 A. No. Well, I at least reviewed those. 4 I would say that I considered them. I wouldn't 5 necessarily say that I relied upon them. 6 Q. And when you consider material, what 7 does that mean to you? 8 A. Well, you know, when I'm -- you can 9 look at my methodology, how I tried to cast as 10 wide a net as possible with the information that 11 I gathered in the information stage. So I wanted 12 to have as much data, as many literature 13 references, expert reports, whatever I could kind 14 of get my hands on that might be relevant to my 15 general causation report. 16 And then I'm reading through those, and 17 that's actually when I started my draft of the 18 report. It really started as sort of notes that 19 I took as I read the different literature 20 references, and I sort of built out from there. 21 Does that answer your question? 22 Q. I think probably so. 23 Did you collect -- did you identify all of 24 the materials in Exhibit 15 yourself, or were 25 some of these provided to you by the plaintiffs'</p>	<p style="text-align: right;">Page 172</p> <p>1 remember, I did my own literature search, read as 2 much as possible, started taking my own notes. 3 And then thought, as I was sort of forming my 4 opinion, thought, you know, it would be nice to 5 know what the defense is saying. And, of course, 6 I think at that point is when I asked, but I 7 don't remember specific timing. 8 Q. And did you specifically -- did you ask 9 for specific defense reports or specific defense 10 reports related to particular expertise? 11 A. If I recall -- I'm looking at this 12 list -- I believe the first request was a more 13 general request. 14 Q. When you say "more general," do you 15 mean for -- 16 A. Meaning -- 17 Q. -- for defense? 18 A. -- I didn't ask for specific names of 19 people. 20 Q. Ah. 21 A. I think at this point, I wasn't 22 necessarily aware of who would have been defense 23 experts. And so I don't remember exactly, but my 24 inclination is that I had asked for a more 25 general sort of representation.</p>
<p style="text-align: right;">Page 171</p> <p>1 counsel? 2 A. The vast majority of them, I found 3 through my own literature search. Some of them 4 may have been supplied by the plaintiffs' 5 attorneys. A lot of those overlapped with what I 6 had already found; the exception, of course, 7 being documents on the other sources that I would 8 not have had access to on my own. 9 So I had asked for, and in forming my 10 opinion, my general causation opinion, I had 11 asked for defense expert reports so I could get a 12 sense of what the defense experts' opinions were, 13 just to get, you know, the other -- just to get 14 more information. 15 So that's -- so those were definitely given 16 to me by plaintiffs' attorneys. 17 Q. Do you remember, timewise, did you 18 review the defense expert reports and the 19 materials in the other sources earlier on to get 20 a sense of the issues in the litigation and then 21 do your literature search, or the other way 22 around? What was the timing? 23 A. I don't remember exactly. I don't 24 believe I read the -- I'm trying to think timing. 25 I think what I did is -- from what I</p>	<p style="text-align: right;">Page 173</p> <p>1 Q. And can you identify on here which of 2 the other sources are from defense experts? 3 A. Yes. I'll try my best. 4 The Michael Ober expert report was provided 5 by plaintiffs' counsel. The deposition of Alice 6 Blount was also provided by plaintiffs' counsel. 7 Both of the Chodosh, his report and his trial 8 testimony, was provided by plaintiffs' counsel. 9 Samuel Cohen was provided by plaintiffs' counsel. 10 And also -- also, let's see, the Cramer, I 11 wouldn't have access to the Cramer reports on the 12 Byrd and Jacqueline Fox. The expert report of 13 Michael Crowley was given to me. That, 14 obviously, is a plaintiffs' report that was 15 within a day or two of turning in my report. 16 That was very late in the process. 17 John Godleski, I might have asked for by 18 name. Of course, he's a plaintiffs' expert. 19 His, I may have asked for by name because of the 20 Cramer papers. 21 Q. Did you say Cramer was a plaintiff or 22 defense expert? 23 A. Cramer, I believe, was a plaintiff. 24 Q. I wasn't sure. You named him after the 25 defense experts. I'm sorry. I'm just going</p>

<p style="text-align: right;">Page 174</p> <p>1 through the list.</p> <p>2 MR. ROTMAN: The list is alphabetical,</p> <p>3 so she's going down the list.</p> <p>4 BY MS. AHERN:</p> <p>5 Q. Yeah. My question was: Which ones are</p> <p>6 the defense experts?</p> <p>7 A. I'm sorry.</p> <p>8 Q. If you're done, you're done. Are there</p> <p>9 any other defense experts.</p> <p>10 A. Well, the John Hopkins and Julie Pier,</p> <p>11 those exhibits and depositions I got from</p> <p>12 plaintiffs' counsel.</p> <p>13 I believe that is it, looking at the list of</p> <p>14 defense reports.</p> <p>15 Q. Did you want to know what the defense</p> <p>16 experts had to say about epidemiology?</p> <p>17 A. I wanted -- yeah. I wanted as much</p> <p>18 evidence as I could get, so --</p> <p>19 Q. Were you aware that the defendants had</p> <p>20 designated epidemiologists in the litigation who</p> <p>21 had given reports and testimony?</p> <p>22 A. I don't know if I was aware</p> <p>23 specifically of that.</p> <p>24 Q. Were you aware that the defense had</p> <p>25 designated a number of gynecologic pathologists</p>	<p style="text-align: right;">Page 176</p> <p>1 ones that I received. Yes.</p> <p>2 Q. Is there anyone on this list that's --</p> <p>3 that specifically addresses gynecologic</p> <p>4 pathology?</p> <p>5 A. I think it's been a long time since I</p> <p>6 read those reports, but I do remember some of</p> <p>7 those reports speaking to -- your question was on</p> <p>8 top. I'm just making sure.</p> <p>9 Q. Sure.</p> <p>10 A. Some -- so the gyn onc report</p> <p>11 definitely went into some gynecologic pathology.</p> <p>12 Gyn oncs are generally knowledgeable about gyn</p> <p>13 pathology because we work pretty closely with</p> <p>14 them. We often show our gyn pathology, for</p> <p>15 example, at multiconferences, multidisciplinary</p> <p>16 conferences.</p> <p>17 So I vaguely remember a gyn onc one going</p> <p>18 over some gyn path stuff, but my memory is vague</p> <p>19 because I have not read these in probably over a</p> <p>20 year. I don't know exactly.</p> <p>21 Q. Would you be interested in what the</p> <p>22 epidemiologists that had served reports and given</p> <p>23 testimony in the litigation the last five years,</p> <p>24 what they've said?</p> <p>25 MR. ROTMAN: Objection.</p>
<p style="text-align: right;">Page 175</p> <p>1 who had given reports and testimony as well?</p> <p>2 A. Again, I don't know if I was</p> <p>3 specifically aware of that. No.</p> <p>4 Q. Would you have, as a pathologist doing</p> <p>5 an expert report on this litigation, would you</p> <p>6 have been interested to know what the defense</p> <p>7 pathologists had said?</p> <p>8 A. Well, I will take any data that I can</p> <p>9 get to try to see if it's relevant. I mean, so I</p> <p>10 had asked for defense reports, and that's what I</p> <p>11 got.</p> <p>12 Q. These reports, these other sources, the</p> <p>13 17 items here were in response to your request,</p> <p>14 but they were chosen by the plaintiffs' counsel?</p> <p>15 MR. ROTMAN: Objection.</p> <p>16 A. I'm not sure how they were chosen or</p> <p>17 how -- why -- all I know is that I asked for</p> <p>18 reports, and this is what I received.</p> <p>19 Q. And you specifically asked for defense</p> <p>20 reports; right?</p> <p>21 A. I did.</p> <p>22 Q. And you got Michael Beer, who is an</p> <p>23 oncologist; Lewis Chodosh, a cancer biologist;</p> <p>24 and Sam Cohen, a toxicologist; correct?</p> <p>25 A. That would appear, from the list, the</p>	<p style="text-align: right;">Page 177</p> <p>1 A. Again, I'll take whatever information</p> <p>2 or data, you know, I can get that might be</p> <p>3 relevant.</p> <p>4 Q. And do you consider expert litigation</p> <p>5 reports to be data?</p> <p>6 A. Yes. I think it's data.</p> <p>7 Q. Okay. Is it the kind of data you rely</p> <p>8 on in your everyday practice as a pathologist?</p> <p>9 A. I sort of view they're opinion reports.</p> <p>10 They're opinion, general causation opinions, and</p> <p>11 a couple of these are -- I can't remember. All</p> <p>12 of these were general, I believe, from the</p> <p>13 defense.</p> <p>14 So they're professional opinion data, and I</p> <p>15 would say that's similar to having a consultation</p> <p>16 with a colleague or a peer. I mean, you know, in</p> <p>17 my day-to-day practice, I'm certainly asking</p> <p>18 opinions of colleagues and different specialties</p> <p>19 or my own specialty, even. Those are</p> <p>20 professional judgments, professional opinions,</p> <p>21 looking at their knowledge of the literature or</p> <p>22 data.</p> <p>23 So I think it's a good analogy; looking at</p> <p>24 general causation, professional opinions, is</p> <p>25 similar to kind of getting a colleague's opinion.</p>

<p style="text-align: right;">Page 178</p> <p>1 Q. But this is the first time you've</p> <p>2 relied on litigation reports to inform your own</p> <p>3 opinions; correct?</p> <p>4 A. Well, again, I don't know if I would</p> <p>5 use the word "rely." I certainly considered</p> <p>6 them, you know. But, again, I think it's very</p> <p>7 similar to asking a colleague in my daily</p> <p>8 practice for an opinion on something.</p> <p>9 Q. And, Doctor, looking at 186 references</p> <p>10 that are cited in Exhibit 15.</p> <p>11 Did you review each one of these carefully</p> <p>12 and thoroughly?</p> <p>13 A. I reviewed each one of them, some of</p> <p>14 them probably more thoroughly than others,</p> <p>15 depending on what I was looking for; but yes, I</p> <p>16 reviewed all of them.</p> <p>17 Q. And do you know whether or not the</p> <p>18 boxes, the four boxes that are sitting behind me,</p> <p>19 do those include these 186 references on</p> <p>20 Exhibit 15?</p> <p>21 MR. TISI: Let me see if I can help you</p> <p>22 out.</p> <p>23 MS. AHERN: Sure. Go ahead.</p> <p>24 MR. TISI: My understanding is they do.</p> <p>25 MS. AHERN: That's the 186?</p>	<p style="text-align: right;">Page 180</p> <p>1 But I don't believe I -- well, I might</p> <p>2 have referenced the Longo.</p> <p>3 BY MS. AHERN:</p> <p>4 Q. Page 5. I think if you look at Page 5</p> <p>5 of your report, you reference Dr. Blount --</p> <p>6 A. Yes.</p> <p>7 Q. -- Dr. Crowley, Longo, Rigler,</p> <p>8 Hopkins --</p> <p>9 A. Yes.</p> <p>10 Q. -- Pier?</p> <p>11 A. Yes. Looking back at the list, you're</p> <p>12 absolutely correct. I did.</p> <p>13 Q. Do you think, as you sit here, that</p> <p>14 those are --</p> <p>15 MR. TISI: I can look at them if it</p> <p>16 makes your life easier. I'm happy to do it.</p> <p>17 But I do think -- Mike is back there</p> <p>18 looking. I'm thinking that those are the actual,</p> <p>19 relied-on referenced materials, not the materials</p> <p>20 considered, which was a separate list.</p> <p>21 MS. AHERN: That's the January 4th, and</p> <p>22 we're going to get to that one.</p> <p>23 MR. TISI: No. it's in the back of the</p> <p>24 report. Maybe I'm wrong.</p> <p>25 MS. AHERN: There are other sources,</p>
<p style="text-align: right;">Page 179</p> <p>1 MR. TISI: That would be the references</p> <p>2 in the report. It would not be, to my -- I</p> <p>3 haven't cracked the boxes, so I can only assume</p> <p>4 from past prologue that the information</p> <p>5 considered is not in those boxes. They may be,</p> <p>6 but the information relied on that is cited in</p> <p>7 the report are.</p> <p>8 MS. AHERN: Okay. So other sources</p> <p>9 here that are not cited specifically, well, they</p> <p>10 may be --</p> <p>11 MR. TISI: I don't know, for example --</p> <p>12 well, maybe we can open them up. But I don't</p> <p>13 know, for example, if the expert reports and</p> <p>14 depositions are in the -- in there. If they're</p> <p>15 cited, then they're probably in there. If</p> <p>16 they're not cited --</p> <p>17 THE WITNESS: I'm not sure because --</p> <p>18 I'm not sure I cited these in my report because</p> <p>19 they weren't necessarily reliance. It was more</p> <p>20 data.</p> <p>21 But I thought at the time that I should</p> <p>22 list what -- because these aren't publicly -- I</p> <p>23 don't believe any of these are publicly</p> <p>24 available, what is on this list, so I felt like I</p> <p>25 should list them.</p>	<p style="text-align: right;">Page 181</p> <p>1 but she has apparently relied on them --</p> <p>2 MR. TISI: That's fine.</p> <p>3 MS. AHERN: -- to some extent in</p> <p>4 performing reviews about fragrances and asbestos.</p> <p>5 BY MS. AHERN:</p> <p>6 Q. Is that right, Doctor?</p> <p>7 A. Dr. Crowley's report and Dr. Longo's</p> <p>8 report, yes. I --</p> <p>9 Q. And what about Dr. Hopkins and Pier?</p> <p>10 A. Yes. I don't believe I read their</p> <p>11 entire depositions. I know I had seen the</p> <p>12 exhibits from the depositions, and I think</p> <p>13 part -- I listed it here, so I must have at some</p> <p>14 point.</p> <p>15 MS. AHERN: Okay. So let's put 15 over</p> <p>16 here, and let's move on to the next one.</p> <p>17 (Document entitled "Additional</p> <p>18 Material Considered" marked Exhibit 16.)</p> <p>19 BY MS. AHERN:</p> <p>20 Q. Okay. Doctor, I'm handing you what's</p> <p>21 been marked as Exhibit 16 to your deposition.</p> <p>22 Can you take a look at Exhibit 16 and tell</p> <p>23 us what that is?</p> <p>24 A. Yes. So this is a combination. So</p> <p>25 once I realized that I needed to give you all a</p>

<p style="text-align: right;">Page 182</p> <p>1 list of -- as complete a list as I could -- I'm 2 not going to say this is a complete list -- and, 3 of course, you have another list that you just 4 got, but I tried to be as complete as I could in 5 recreating the literature and other reports that 6 I had considered. 7 So these are ones that, to my recollection, 8 I didn't specifically cite or were not 9 available -- I mean, obviously, I have some of 10 the plaintiffs' expert reports that weren't 11 available to me until after I had written and 12 submitted my report. So some of these were 13 available to me only after -- and the Health 14 Canada came out after my report. 15 So these are a combination of things I 16 reviewed subsequent to November 15th and stuff 17 that I had reviewed prior to that but had not 18 specifically cited and recreated the list. 19 Q. Okay. And just for the record, this 20 is -- Exhibit 16 is a four-page document. It's 21 not paginated, but it has 96 items identified as 22 "Additional Materials Considered," so -- served 23 on January 4, 2018. 24 Can you identify, as you look through these 25 items on Exhibit 16, which of those you reviewed</p>	<p style="text-align: right;">Page 184</p> <p>1 A. No. 2 Q. And are there some materials on 3 Exhibit 16 that were provided to you or 4 identified for you by the plaintiffs other 5 than -- and I'm not talking about the litigation 6 materials, but the articles? 7 A. Again, there might have been some that 8 overlapped with what I had already found. I'm 9 looking. 10 I believe the April 2014 FDA letter may -- 11 although that might have been available on the 12 internet. I might have come across that on my 13 own first. 14 No. I believe the vast majority of this 15 stuff was stuff that I -- other than those 16 reports was stuff that I had independently 17 already found. That's the only one that is 18 ringing a bell as a possibility, but I also seem 19 to remember finding it on the internet. 20 Q. Okay. And are any of these materials, 21 materials that you explicitly rely on or, excuse 22 me, are any of the materials on Exhibit 16 23 materials that you rely on to support your 24 opinions? 25 A. Again, it's all data that I considered.</p>
<p style="text-align: right;">Page 183</p> <p>1 prior to the submission of your report and which 2 ones you reviewed after? 3 A. I can do the best that I can. My 4 memory might be a little -- and I have to jog my 5 memory a little bit on some of them. 6 Clearly, the expert reports that were 7 dated -- the plaintiff expert reports that were 8 dated after my report, I had not seen -- 9 Q. Mm-hmm. 10 A. -- prior. 11 And, again, the Health Canada came out 12 afterwards, so that was not available when I 13 submitted my report. The majority of the rest of 14 the literature, I had read prior to submitting my 15 report. 16 Q. Okay. Had you seen any draft reports 17 from any of the other experts designated by the 18 plaintiffs in this litigation? 19 A. Not before my report. I didn't see any 20 drafts. I only saw the final reports after my 21 report was submitted. 22 Q. Okay. Did you have an opportunity to 23 talk with any of the other experts that were 24 designated by plaintiffs prior to your report 25 being submitted?</p>	<p style="text-align: right;">Page 185</p> <p>1 I didn't specifically cite them, but there's 2 certainly pieces of information that helped me 3 come to my conclusion. 4 Q. And you prepared Exhibit 16, didn't 5 you? 6 A. Yes. 7 Q. And do you remember when you prepared 8 it? 9 A. Very shortly before you received it. 10 So it would have been -- you received it 11 January 4th? 12 Q. Mm-hmm. 13 A. I think I -- it was only -- I don't 14 remember exactly, but it wasn't very long before 15 that that I put it all together, after 16 recreating -- trying to recreate as best I could 17 the list of literature that I had reviewed. 18 Q. And did you carefully and completely 19 review all of the information in Exhibit 16? 20 A. Again, I reviewed all of it. Some of 21 it was more relevant than others, likely, so -- 22 but I reviewed all of them. 23 Q. Okay. Obviously, anything that you 24 received after your report is information you 25 would not have relied on to form your opinions in</p>

<p style="text-align: right;">Page 186</p> <p>1 this case; correct?</p> <p>2 A. No. It's more information for my -- my</p> <p>3 opinion hasn't changed since I wrote my report.</p> <p>4 In fact, I know we've talked about Health Canada</p> <p>5 a little bit, but that was pretty interesting to</p> <p>6 see that report because their methodology was</p> <p>7 very similar to mine, and they did a Bradford</p> <p>8 Hill analysis, and they looked at a lot of the</p> <p>9 same literature and came to the same conclusion.</p> <p>10 So that definitely was supportive evidence,</p> <p>11 I think -- not I think; it is -- of my opinion.</p> <p>12 Q. And, Doctor, I only have one copy of</p> <p>13 this. It's "Additional Materials to Sarah Kane"</p> <p>14 that were served last night or yesterday</p> <p>15 afternoon, January 24th.</p> <p>16 (Document entitled "Additional</p> <p>17 Materials to Dr. Sarah Kane" marked Exhibit</p> <p>18 17.)</p> <p>19 BY MS. AHERN:</p> <p>20 Q. First of all, can you take a look at</p> <p>21 that?</p> <p>22 Have you seen it before?</p> <p>23 A. Yes. Yes. I have.</p> <p>24 Q. Did you prepare that?</p> <p>25 A. I did. I had listed -- there are a</p>	<p style="text-align: right;">Page 188</p> <p>1 I think that covers most of them.</p> <p>2 Q. What about the EFSA guidance on the use</p> <p>3 of weight of evidence?</p> <p>4 A. Oh, yeah. That, I think, I reviewed</p> <p>5 after I had submitted my report.</p> <p>6 Q. Did that form part of the basis of your</p> <p>7 opinions or your methodology?</p> <p>8 A. It was more of a -- it basically shows</p> <p>9 that the methodology that I used is very similar</p> <p>10 to evidence-based medicine that we would use on a</p> <p>11 daily basis. It kind of went through weight of</p> <p>12 evidence, and it was sort of helpful to see the</p> <p>13 similarity of the methodology that I used coming</p> <p>14 to my conclusion.</p> <p>15 Q. Was the methodology you used for</p> <p>16 preparing your opinions in this case and your</p> <p>17 report in this case taken directly from the EFSA</p> <p>18 guidance?</p> <p>19 A. No. I think I just -- I saw this EFSA</p> <p>20 guidance after writing my report.</p> <p>21 Q. Did you use any other sort of published</p> <p>22 methodology on weight of the evidence when you</p> <p>23 prepared your opinions?</p> <p>24 A. I used what we have been trained to</p> <p>25 use. I mean, it's evidence. It's an</p>
<p style="text-align: right;">Page 187</p> <p>1 couple of papers that I realize I had read</p> <p>2 previously and didn't -- I can tell you Purdie,</p> <p>3 1995, Keskin, 2009, I definitely reviewed while</p> <p>4 preparing my report, and somehow those got off</p> <p>5 the list.</p> <p>6 The other ones, Taher wasn't available. I'm</p> <p>7 trying to remember Gordon, if I had seen that.</p> <p>8 If I had seen that before I submitted a report,</p> <p>9 it was very late. It might have been after.</p> <p>10 The IARC heavy metals, I believe I actually</p> <p>11 cited that in my reference list, but I was trying</p> <p>12 to be -- it was one of these last-minute, trying</p> <p>13 to be as complete as possible, so that actually</p> <p>14 might be a repeat.</p> <p>15 The website, I had reviewed prior to turning</p> <p>16 in my report. And the Longo supplemental report,</p> <p>17 obviously, wasn't available until January. Same</p> <p>18 with the depositions. Those weren't available</p> <p>19 until after they were done.</p> <p>20 The Kurman defense report, I asked for</p> <p>21 recently when I realized that Kurman was a</p> <p>22 listed -- a named expert witness, which is also</p> <p>23 why I went through my copies of my old textbooks</p> <p>24 and my partner's old textbooks. So that, I asked</p> <p>25 for specifically.</p>	<p style="text-align: right;">Page 189</p> <p>1 evidence-based medicine model of methodology and</p> <p>2 coming to conclusions. So it's -- I tried to do</p> <p>3 as thorough as possible description of my</p> <p>4 methodology, which we can refer to in my report</p> <p>5 if you'd like.</p> <p>6 Q. What about the J&J Science Day</p> <p>7 presentation?</p> <p>8 A. That --</p> <p>9 MR. ROTMAN: Objection. Is there a</p> <p>10 question?</p> <p>11 MS. AHERN: I'm about to get there if</p> <p>12 you'd let me finish my question.</p> <p>13 MR. ROTMAN: I thought you were.</p> <p>14 Sorry.</p> <p>15 MS. AHERN: You might just hold off.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. What about the J&J Science Day</p> <p>18 presentation? Is that something that you</p> <p>19 reviewed?</p> <p>20 A. I reviewed that very quickly, and I</p> <p>21 only received that maybe a week ago. It was very</p> <p>22 recently.</p> <p>23 Q. Did you request that information?</p> <p>24 A. I think, from what I remember, it was</p> <p>25 part of asking for more sort of defense side of</p>

<p style="text-align: right;">Page 190</p> <p>1 the story; what, you know, your experts might 2 have been saying; what kind of -- you know, I was 3 trying to figure out how somebody who had looked 4 at the same body of evidence that I did can come 5 to a different conclusion, so it was part of sort 6 of that request.</p> <p>7 I think I probably got it after I requested 8 Kurman's defense report from a prior litigation, 9 if memory serves me correctly.</p> <p>10 Q. You would agree that a very large part, 11 not just volume, but a very large part of your 12 report and your opinions in this case are related 13 to the observational epidemiology on talc and 14 ovarian cancer; is that correct?</p> <p>15 A. Well, I think that epidemiology 16 literature is extremely compelling. You have 17 30 case-control studies over different periods of 18 time in different populations that have come to 19 the same -- same ballpark relative risk, I would 20 say, 1.3 to 1.4.</p> <p>21 Now, not all of those have been 22 statistically significant, but some of those 23 studies were smaller studies, and so that tends 24 to decrease the power of the study and your 25 confidence intervals will be wider.</p>	<p style="text-align: right;">Page 192</p> <p>1 is such a rare disease, and you're sort of, you 2 know, rolling the dice when you enroll patients 3 as to whether or not they're going to end up with 4 a disease at the end that you want to study.</p> <p>5 So you're sort of -- and these cohorts are 6 also designed for multiple endpoints and multiple 7 diseases. They weren't just looking, most of 8 them -- I believe the sister -- well, the sister 9 study -- anyway, we can pull it out if I have to, 10 but my point is the cohort studies are designed 11 for multiple different things, especially the 12 Nurses' Health Study.</p> <p>13 And so it's a difficult type of study to 14 design with a very rare disease. And I think 15 that's where the case-control studies are 16 important because you can start with the disease 17 and work backwards, and so you can have an easier 18 time getting cases.</p> <p>19 Q. Did you find it interesting or odd that 20 you were provided with a number of defense expert 21 reports, but not a single one of them related to 22 the epidemiology specifically from an 23 epidemiologist?</p> <p>24 A. Well, you know, again, I don't pretend 25 to know why I was sent what I was sent. I just</p>
<p style="text-align: right;">Page 191</p> <p>1 But I thought the epi data was really 2 compelling. And often in causation, the epi data 3 sort of leads the way in paving a path to 4 figuring out causation.</p> <p>5 A perfect example is tobacco. You know, the 6 Surgeon General issued his report in the 1960s 7 about tobacco before they had any mechanism for 8 tobacco causing -- so that was a perfect example 9 of the epi data leading to causation.</p> <p>10 So it's true, a lot of the studies looking 11 at talcum powder products and ovarian cancer are 12 epidemiology studies, but they're extremely 13 informative in that they are very consistent in 14 their findings. And, again, different authors, 15 different populations, different countries.</p> <p>16 And there's also the cohort. So I went 17 through the cohort studies. The cohort studies, 18 some of them showed an association with serous 19 invasive carcinoma, but the cohort studies didn't 20 tend to find, other than that, a statistically 21 significant increased risk, although some of them 22 did find increased risk.</p> <p>23 But we can talk about cohort studies versus 24 case-control studies if you want, but I think the 25 difficulty with cohort studies is ovarian cancer</p>	<p style="text-align: right;">Page 193</p> <p>1 know that I asked for reports, and I got what I 2 got. So I have no idea what the process was in 3 deciding what I received; if there was even a 4 decision. For all I know, it's just what they 5 had readily available.</p> <p>6 Sorry. What is the question?</p> <p>7 Q. Well, let me ask another question.</p> <p>8 MR. ROTMAN: Let her finish the answer 9 because you can read -- she can go back and read 10 from the realtime what the question was and see 11 if she's done.</p> <p>12 A. So I guess I don't know if there was 13 thinking -- what the thinking was or if there was 14 any. But also I can say that the epi data -- I 15 knew that by that point that the epi data was 16 consistent by the time I -- I think that was the 17 first literature that I was looking at, and so I 18 knew that it was consistent.</p> <p>19 So it's -- anyway, I don't really -- I don't 20 know is the answer, the short answer.</p> <p>21 The long answer, the short answer is I don't 22 know why I got what I did. I just did.</p> <p>23 Q. Okay. And you've seen the designations 24 in this case from November of 2017 in which you 25 were listed formally and publicly as an expert</p>

<p style="text-align: right;">Page 194</p> <p>1 for the MDL? Have you seen that document?</p> <p>2 A. I'm not sure that I have, actually.</p> <p>3 Q. Were you aware that in November of</p> <p>4 2017, you were listed on a court document as an</p> <p>5 expert for the plaintiffs in the MDL litigation?</p> <p>6 MR. ROTMAN: Objection.</p> <p>7 A. I don't know the timing or I don't</p> <p>8 think I saw the document, so I...</p> <p>9 ("The Plaintiffs' Steering</p> <p>10 Committee's Initial Designation and</p> <p>11 Disclosure of Non-case Specific Expert</p> <p>12 Witnesses" marked Exhibit 18.)</p> <p>13 BY MS. AHERN:</p> <p>14 Q. Okay. I'm marking Exhibit 18 to your</p> <p>15 deposition. Do you see this document,</p> <p>16 Exhibit 18, is entitled "Plaintiff Steering</p> <p>17 Committee's Initial Designation and Disclosure of</p> <p>18 Non-case Specific Expert Witnesses"?</p> <p>19 A. Okay.</p> <p>20 Q. And if you turn to -- first of all,</p> <p>21 let's see. Unfortunately, I can't find the date</p> <p>22 on that, and I apologize.</p> <p>23 MR. TISI: It's January, if I'm not</p> <p>24 mistaken. I think it was mid-January of 2017.</p> <p>25 MS. AHERN: Is that what it is?</p>	<p style="text-align: right;">Page 196</p> <p>1 MR. TISI: That's fine.</p> <p>2 MS. AHERN: Absolutely.</p> <p>3 I have the date as November 6, 2017.</p> <p>4 MR. TISI: You are exactly -- well, it</p> <p>5 is what it is.</p> <p>6 MS. AHERN: Okay. Either way.</p> <p>7 BY MS. AHERN:</p> <p>8 Q. Okay. Doctor, if you turn to -- if you</p> <p>9 turn to Page 8, the bottom of Page 8, do you see</p> <p>10 your name?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And did you -- go ahead and</p> <p>13 review the text here associated with your name</p> <p>14 and designation.</p> <p>15 (Witness complies.)</p> <p>16 Q. Just let me know when you're finished.</p> <p>17 A. I'm finished reading my blurb. I'm</p> <p>18 just looking...</p> <p>19 Q. Sure.</p> <p>20 A. Okay.</p> <p>21 Q. Were you aware in November of 2017 that</p> <p>22 you had been publicly disclosed as an expert on</p> <p>23 behalf of plaintiffs in the MDL?</p> <p>24 MR. TISI: Okay. That's -- and you do</p> <p>25 kind of need to know the context in which this</p>
<p style="text-align: right;">Page 195</p> <p>1 MR. TISI: Yeah. And, Counsel, since I</p> <p>2 was involved in this process, if you don't mind</p> <p>3 if I place an objection here.</p> <p>4 MS. AHERN: Sure.</p> <p>5 MR. TISI: As you may not know, during</p> <p>6 the status conference where this was ordered -- I</p> <p>7 don't have the transcript in front of me -- it</p> <p>8 was intended to be an interim -- I don't know</p> <p>9 what the questions are going to be, but it was</p> <p>10 intended to be an interim disclosure to help</p> <p>11 guide the legal process for identifying issues</p> <p>12 that would be involved in Judge Wolfson looking</p> <p>13 at the science.</p> <p>14 It was never -- I don't know -- again,</p> <p>15 not knowing what your questions are, I don't even</p> <p>16 think it would be intended to be used as an</p> <p>17 expert -- as an exhibit in a deposition.</p> <p>18 But, you know, whatever your questions</p> <p>19 are, we would like to reserve that because --</p> <p>20 MS. AHERN: Sure.</p> <p>21 MR. TISI: -- this was intended to be</p> <p>22 a -- more of an informative document than</p> <p>23 anything else.</p> <p>24 MS. AHERN: Okay. Your objection is</p> <p>25 noted.</p>	<p style="text-align: right;">Page 197</p> <p>1 was done.</p> <p>2 MS. AHERN: I'm just asking if she was</p> <p>3 aware she was publicly -- she was already</p> <p>4 retained at that point.</p> <p>5 MR. TISI: She was retained, but there</p> <p>6 was no -- the judge was very clear when she</p> <p>7 ordered that this be done. She understood that</p> <p>8 this was not a disclosure of experts.</p> <p>9 So when you ask the question "You</p> <p>10 understand you were being identified as an expert</p> <p>11 at that time," she would have no way of knowing</p> <p>12 that because we didn't know it.</p> <p>13 MR. KLATT: Chris, you've got to limit</p> <p>14 your objection.</p> <p>15 MR. TISI: No. But it's unfair</p> <p>16 because --</p> <p>17 MR. KLATT: You're coaching the</p> <p>18 witness. You're telling her the whole story.</p> <p>19 MR. TISI: It's a true story. Why</p> <p>20 don't we ask her to leave, and we'll put it on</p> <p>21 the record. I have no problem with that.</p> <p>22 MR. KLATT: All right.</p> <p>23 MR. TISI: We can ask her to leave, and</p> <p>24 we can put it on the record.</p> <p>25 MR. KLATT: Let's do that.</p>

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<p style="text-align: right;">Page 198</p> <p>1 MR. ROTMAN: Go get a cookie.</p> <p>2 MS. AHERN: Sorry, doctor.</p> <p>3 (Witness exited)</p> <p>4 MS. AHERN: My questions on this are</p> <p>5 fairly limited to the time period that she was</p> <p>6 retained, time period she was intending to be an</p> <p>7 expert, that sort of thing --</p> <p>8 MR. TISI: Yeah.</p> <p>9 MS. AHERN: -- and the subject matter</p> <p>10 that she is being designated for.</p> <p>11 MR. TISI: Yeah. But, you see, the</p> <p>12 issue in the case -- and the reason why this was</p> <p>13 a tricky issue for the judge and -- well, I won't</p> <p>14 speak for the judge, but for us when we disclosed</p> <p>15 this was because we didn't know -- we didn't have</p> <p>16 expert reports. We didn't even have opinions</p> <p>17 yet.</p> <p>18 So this was being done in a way that</p> <p>19 said, "Okay, Judge, she wants to know, A, are</p> <p>20 there new and different witnesses that were going</p> <p>21 to be designated that were different than what</p> <p>22 was designated in the state court?"</p> <p>23 MS. AHERN: I do recall this, yes.</p> <p>24 MR. TISI: The second issue, she was</p> <p>25 very clear that she understood that there was a</p>	<p style="text-align: right;">Page 200</p> <p>1 MR. TISI: She was probably not, I</p> <p>2 mean, what she was aware of when she had been</p> <p>3 retained.</p> <p>4 MS. AHERN: Did she agree to be</p> <p>5 disclosed as an expert?</p> <p>6 MR. TISI: She agreed to be retained.</p> <p>7 She was disclosed as an expert when she reached</p> <p>8 her conclusions in the case.</p> <p>9 And so what the Court was requiring us</p> <p>10 to do was to give us a broad brush, and she was</p> <p>11 very clear. I remember standing in court, and</p> <p>12 she said, "Look, some of these may fall off your</p> <p>13 list. Some of these may -- we may have people</p> <p>14 that might be added, but I want a snapshot in</p> <p>15 time as to what I'm dealing with in terms of" --</p> <p>16 MR. KLATT: We don't need to waste time</p> <p>17 on the record on this.</p> <p>18 MR. TISI: We can go off the record if</p> <p>19 you want. I just don't want to be -- use this as</p> <p>20 an unfair -- you know, none of your questions</p> <p>21 have been unfair up until now.</p> <p>22 But to take this document and to</p> <p>23 suggest in some fashion -- and I don't know what</p> <p>24 you're going to do with it. Maybe we just need</p> <p>25 to wait and see.</p>
<p style="text-align: right;">Page 199</p> <p>1 lot of discovery that needed to be done,</p> <p>2 documents to be reviewed, science that was going</p> <p>3 to come out. So she was pretty clear that this</p> <p>4 was more informative than anything else.</p> <p>5 And so when you ask her a question</p> <p>6 about -- when you ask her questions, "You know</p> <p>7 when this document was disclosed when you were</p> <p>8 identified as an expert," you know, it implies</p> <p>9 that she had agreed to be -- you know, what her</p> <p>10 opinions actually were at that time.</p> <p>11 She -- I can tell you that these</p> <p>12 reports were done over a period of time. So it's</p> <p>13 misleading, and it really is an unfair thing to</p> <p>14 do to a witness because this was a court request</p> <p>15 having nothing to do with her opinions or her</p> <p>16 expert report.</p> <p>17 MS. AHERN: Okay.</p> <p>18 MR. TISI: Do you understand where I'm</p> <p>19 coming from?</p> <p>20 MS. AHERN: I understand where you're</p> <p>21 coming from.</p> <p>22 Here is my question to you: Did Dr. --</p> <p>23 was Dr. Kane not aware that you were going to</p> <p>24 designate her or that you had at least publicly</p> <p>25 disclosed her to the Court?</p>	<p style="text-align: right;">Page 201</p> <p>1 But I think this is -- I don't think</p> <p>2 anyone ever intended that this document would be</p> <p>3 used as an exhibit in a deposition of one of</p> <p>4 these witnesses. I don't think the court</p> <p>5 intended that to be the case, just like she --</p> <p>6 when she ordered the Tardek report --</p> <p>7 informational only.</p> <p>8 MR. KLATT: Are we off the record?</p> <p>9 We're just going on here. Let's go off the</p> <p>10 record.</p> <p>11 MR. TISI: Yeah.</p> <p>12 THE VIDEOGRAPHER: Off the record,</p> <p>13 2:38 p.m.</p> <p>14 (A recess was taken.)</p> <p>15 THE VIDEOGRAPHER: Back on the record,</p> <p>16 2:42 p.m.</p> <p>17 (Witness returns)</p> <p>18 BY MS. AHERN:</p> <p>19 Q. Okay. Doctor, I've just shown you a</p> <p>20 copy of some early designations that were</p> <p>21 submitted in the talc MDL, and you saw your name</p> <p>22 listed as one of the people who was being</p> <p>23 considered as an expert; correct?</p> <p>24 A. My name is in this document. Yes.</p> <p>25 Q. Okay. Is there any -- do you have any</p>

<p style="text-align: right;">Page 202</p> <p>1 issues with the description of the testimony that</p> <p>2 you were going to offer to give?</p> <p>3 A. I believe that to be accurate.</p> <p>4 Q. Okay. And you had been working on your</p> <p>5 report at this point since May of 2017; correct?</p> <p>6 A. I started in May. "Writing the report"</p> <p>7 is a very loose description. What I was -- what</p> <p>8 I started, as I mentioned before, was I started</p> <p>9 to review literature. I sort of took notes. So</p> <p>10 I sort of counted that as writing. So I started</p> <p>11 that process in May.</p> <p>12 Q. Okay. And the only thing I was going</p> <p>13 to ask you about in this report is, as you look</p> <p>14 through it, do you note that there are a number</p> <p>15 of professional epidemiologists that have been</p> <p>16 listed in this report on behalf of plaintiffs?</p> <p>17 A. I'd have to go through the list. I</p> <p>18 actually, even though I did have access to</p> <p>19 several final reports, after I had submitted my</p> <p>20 report, I don't remember who was what specialty,</p> <p>21 what field, for the majority of them.</p> <p>22 Q. Well, how about this question: Of the</p> <p>23 experts -- are you aware of which experts have</p> <p>24 submitted reports on behalf of the plaintiffs?</p> <p>25 A. I would need to look at the list that I</p>	<p style="text-align: right;">Page 204</p> <p>1 asked me if I would be willing to do an extensive</p> <p>2 review of the literature and decide what my</p> <p>3 opinion would be on talcum powder products</p> <p>4 causing ovarian cancer.</p> <p>5 Q. Did you ask them or discuss with them</p> <p>6 what your role would be in terms of your specific</p> <p>7 area of expertise in anatomic pathology?</p> <p>8 A. I did not specifically talk to them</p> <p>9 about that because I know that I'm a gynecologic</p> <p>10 pathologist, so I thought that would be my area</p> <p>11 where I weigh in on my opinion.</p> <p>12 Q. And where in your report specifically</p> <p>13 do you address your expertise in gynecologic</p> <p>14 pathology, anatomic pathology?</p> <p>15 A. I list it in the beginning of my</p> <p>16 report, I think. I talk about -- I talk about my</p> <p>17 background.</p> <p>18 Is that what you mean?</p> <p>19 Q. I mean more in terms of the opinions</p> <p>20 that you're giving being informed by your</p> <p>21 expertise in anatomic pathology.</p> <p>22 A. Well, again, I'm an expert in</p> <p>23 gynecologic pathology, and the question is about</p> <p>24 a causation of ovarian cancer, so certainly that</p> <p>25 falls into my area of expertise.</p>
<p style="text-align: right;">Page 203</p> <p>1 reviewed, which I think is all of the ones that</p> <p>2 were submitted, and compare it to this list.</p> <p>3 I mean, I know Jack Siemiatycki is an</p> <p>4 epidemiologist, off the top of my head.</p> <p>5 Dr. Singh, I believe, is an epidemiologist.</p> <p>6 But without going through the list and sort</p> <p>7 of jogging my memory as to the reports, I skimmed</p> <p>8 a lot of these reports.</p> <p>9 Q. Okay. And I guess the point is: Are</p> <p>10 you aware, as we sit here today, that the</p> <p>11 plaintiffs have designated a number of</p> <p>12 epidemiologists in this MDL litigation who have</p> <p>13 given reports and/or testimony at this point on</p> <p>14 the topic of epidemiology, talc and ovarian</p> <p>15 cancer?</p> <p>16 A. I am aware that they have</p> <p>17 epidemiologists that have submitted reports for</p> <p>18 this MDL.</p> <p>19 Q. Okay. And specifically, if you can</p> <p>20 think back to your initial contact with</p> <p>21 plaintiffs' counsel when you were asked to get</p> <p>22 involved in the litigation, what specifically</p> <p>23 were you asked to do, or what was your</p> <p>24 understanding of what your role would be?</p> <p>25 A. Yeah. My understanding was they had</p>	<p style="text-align: right;">Page 205</p> <p>1 Q. And do you specifically address in</p> <p>2 terms of anatomic pathology or ovarian cancer</p> <p>3 pathogenesis the question of talc and ovarian</p> <p>4 cancer?</p> <p>5 A. I think that goes to the plausibility,</p> <p>6 the mechanisms, as part of it.</p> <p>7 Q. And which particular mechanisms are</p> <p>8 informed by the discipline of anatomic pathology</p> <p>9 and gynecologic pathology?</p> <p>10 A. Well, I think pathologists, anatomical</p> <p>11 and clinical pathologists, have training in</p> <p>12 inflammation and immunology and certainly</p> <p>13 epidemiology, looking at epidemiologic studies.</p> <p>14 I think all of it is within the realm of</p> <p>15 gynecologic pathology.</p> <p>16 Q. Did you discuss anywhere specifically</p> <p>17 in your report the biology of foreign body</p> <p>18 reactions and granulomas as a part of the</p> <p>19 biologic plausibility for exposure?</p> <p>20 A. Let me refer to my report. I</p> <p>21 definitely talk about inflammation. I can do a</p> <p>22 word search for granulomas, if you would like.</p> <p>23 Q. Do you talk about inflammation --</p> <p>24 MR. ROTMAN: Would you like --</p> <p>25 Q. -- in the context of anatomic</p>

<p style="text-align: right;">Page 206</p> <p>1 pathology?</p> <p>2 MR. ROTMAN: Would you like to do that?</p> <p>3 Because I can get your report up electronically.</p> <p>4 MS. AHERN: I know where she's</p> <p>5 mentioned granulomas. I already know. I'm just</p> <p>6 asking her if she knows.</p> <p>7 MR. ROTMAN: So she wants to find it</p> <p>8 quickly.</p> <p>9 MS. AHERN: You can give her your</p> <p>10 computer and let her search.</p> <p>11 MR. ROTMAN: Okay. That's what I was</p> <p>12 asking.</p> <p>13 BY MS. AHERN:</p> <p>14 Q. Do you cite any publications describing</p> <p>15 the biology of granulomas?</p> <p>16 A. I know some of the literature talks</p> <p>17 about granulomatous inflammation, discusses</p> <p>18 granulomatous inflammation.</p> <p>19 MR. ROTMAN: If you want to search, do</p> <p>20 you know how to do it on this computer? Edit,</p> <p>21 Find, then you can type in a word that you want</p> <p>22 to search.</p> <p>23 MR. KLATT: Is there a question?</p> <p>24 A. So I mention it in the animal studies,</p> <p>25 injecting talc into the pleural spaces causes</p>	<p style="text-align: right;">Page 208</p> <p>1 any other portions of your report that directly</p> <p>2 address ovarian cancer pathogenesis from a</p> <p>3 pathology standpoint," and --</p> <p>4 A. So my answer is I did the work, but I</p> <p>5 can't discuss it because of attorney work product</p> <p>6 issues.</p> <p>7 Q. Okay.</p> <p>8 MR. ROTMAN: You can -- she can -- you</p> <p>9 can ask her questions about it.</p> <p>10 MS. AHERN: Sure.</p> <p>11 MR. ROTMAN: But she's -- as to what is</p> <p>12 in the report or not in the report, that's the</p> <p>13 work product piece.</p> <p>14 MS. AHERN: That's kind of all the</p> <p>15 questions.</p> <p>16 MR. ROTMAN: Ask her about the science.</p> <p>17 MS. AHERN: I'll ask, and you can</p> <p>18 object.</p> <p>19 MR. KLATT: Find out what is in or is</p> <p>20 not in the report.</p> <p>21 MS. AHERN: Let's pick up the</p> <p>22 foundation here.</p> <p>23 BY MS. AHERN:</p> <p>24 Q. Doctor, first of all, you said you did</p> <p>25 the work relating to ovarian cancer pathogenesis</p>
<p style="text-align: right;">Page 207</p> <p>1 granulomatous response. It looks like those are</p> <p>2 the two.</p> <p>3 And then I cite the Mostafa 1985 paper,</p> <p>4 "Foreign body granulomas in normal ovaries."</p> <p>5 I'm double-checking. It looks like in doing</p> <p>6 a word search for granuloma, that's what is</p> <p>7 popping up.</p> <p>8 BY MS. AHERN:</p> <p>9 Q. Okay. Are there any other portions of</p> <p>10 your report that directly address ovarian cancer</p> <p>11 pathogenesis from a pathology standpoint?</p> <p>12 MR. ROTMAN: Objection.</p> <p>13 A. This might be attorney work product</p> <p>14 draft stuff.</p> <p>15 MR. ROTMAN: Do you want to talk to me</p> <p>16 outside where I can understand what you're</p> <p>17 getting at?</p> <p>18 THE WITNESS: Sure. Sure.</p> <p>19 THE VIDEOGRAPHER: Off the record,</p> <p>20 2:50 p.m.</p> <p>21 (A recess was taken.)</p> <p>22 THE VIDEOGRAPHER: Back on the record,</p> <p>23 2:54 p.m.</p> <p>24 BY MS. AHERN:</p> <p>25 Q. Okay. Doctor, I had asked: "Are there</p>	<p style="text-align: right;">Page 209</p> <p>1 from a pathology standpoint; correct?</p> <p>2 A. Yes.</p> <p>3 Q. Was it ever in your report?</p> <p>4 MR. ROTMAN: That's part of the work</p> <p>5 product objection.</p> <p>6 MR. KLATT: We've got to establish the</p> <p>7 facts to know whether there's a basis to assert</p> <p>8 the objection.</p> <p>9 MR. ROTMAN: You can ask the question.</p> <p>10 But in order to answer the question, you're</p> <p>11 invading the domain of what is protected under</p> <p>12 the Federal Rules in terms of the drafting of</p> <p>13 expert reports.</p> <p>14 I will object and instruct her not to</p> <p>15 answer.</p> <p>16 What's in the report, you have. What</p> <p>17 was in drafts of the report, you're not entitled</p> <p>18 to.</p> <p>19 So that's the problem we have.</p> <p>20 MR. KLATT: She's not asking what was</p> <p>21 in the report. She's asking whether it was or</p> <p>22 isn't. So we can establish if there's anything</p> <p>23 to even have a dispute about.</p> <p>24 MR. ROTMAN: You can ask her about what</p> <p>25 is in the report all you want.</p>

<p style="text-align: right;">Page 210</p> <p>1 MS. AHERN: Well, she's already said 2 there was a section on ovarian cancer 3 pathogenesis from a pathology standpoint in the 4 report, and it was removed; correct? 5 MR. TISI: That's not what she 6 testified. 7 MS. AHERN: Read back. 8 MR. TISI: Why don't we read what she 9 said because she said the answer is: 10 "ANSWER: I did the work, but I can't 11 discuss it because of attorney work product." 12 MS. AHERN: Okay. Okay. 13 MR. TISI: She never said it was in the 14 report. 15 MS. AHERN: Thank you. 16 MR. TISI: Line 48. 17 BY MS. AHERN: 18 Q. When you say you "did the work," did 19 you take any notes on any reading that you did on 20 ovarian cancer pathogenesis? 21 A. So in writing this report, I generally 22 did not take any notes, handwritten notes. It 23 was sort of a living document that I used. 24 Q. Now, earlier, you referred several 25 times to taking notes as you were going through</p>	<p style="text-align: right;">Page 212</p> <p>1 let me rephrase it. 2 As a gynecologic pathologist who was asked 3 to opine on ovarian cancer and talc, did you 4 assume that part of your opinions would be to 5 incorporate your expertise in anatomic pathology 6 and gynecologic pathology? 7 MR. ROTMAN: Wait. Wait. Wait. Wait. 8 Wait. 9 MS. AHERN: I'm only concerned if she 10 understands the question. 11 BY MS. AHERN: 12 Q. Do you understand the question? 13 MR. ROTMAN: No. You have to let me 14 see if I understand the question to see if I'm 15 going to object to it before she's allowed to 16 answer. 17 MS. AHERN: Why don't you make an 18 objection, and we'll move on. 19 MR. TISI: Because he may instruct her 20 not to answer the question. 21 MS. AHERN: This is not -- this is not 22 a question that should invade your privilege. 23 MR. TISI: It involves the discussion 24 between counsel and in the drafting of the 25 reports, what would be in, what would be out,</p>
<p style="text-align: right;">Page 211</p> <p>1 literature. 2 Are all those notes something that became -- 3 on a single document that ultimately became a 4 report? 5 A. It was one document that went through 6 numerous, numerous editing on my part and, of 7 course, suggestions from attorneys at different 8 points. 9 Q. Now, as an anatomic pathologist and as 10 the only pathologist that has been designated by 11 the plaintiffs in this MDL, did you think that it 12 was important to opine on the pathogenesis of 13 ovarian cancer from an anatomic pathology 14 standpoint? 15 MR. ROTMAN: Objection. For what 16 purpose? 17 MS. AHERN: I'm asking her. 18 Q. Can you answer the question? 19 A. First of all, I wasn't aware I was the 20 only pathologist because I didn't have a list of 21 their named experts. 22 I did work on -- I'm not sure how much I can 23 really talk about the whole draft process. 24 MR. ROTMAN: You can't -- 25 Q. So my question was: As an anatomic --</p>	<p style="text-align: right;">Page 213</p> <p>1 what she thought, what she didn't think. You're 2 not entitled to any of that. 3 MR. ROTMAN: So if you can find the 4 question, read the question, and I will object to 5 the question, but you can answer it. 6 A. Okay. So you want me to reread the 7 question? 8 MR. ROTMAN: To yourself. 9 So my question was -- do you see that? 10 THE WITNESS: Yeah. 11 A. Well, I feel as if I did that in my 12 final report. I certainly -- the -- my opinions 13 that are in my final report are certainly within 14 the realm of gynecologic pathology. 15 Q. And can you specifically point to the 16 opinions and the discussions in your report that 17 are within your personal expertise in gynecologic 18 pathology? 19 A. So, again, review of epidemiology is 20 something that physicians do on a regular basis. 21 We're trained to look at epi data. We're trained 22 to practice evidence-based medicine, which has a 23 very similar, if not identical, methodology. 24 So -- and we certainly are trained in 25 inflammation, the immune system, talc and</p>

<p style="text-align: right;">Page 214</p> <p>1 tissue -- I have a section on talc and tissue -- 2 the epi data. 3 Not -- I don't think any of this report is 4 outside of my -- I know that none of this is 5 outside of my expertise as a gynecologic 6 pathologist. 7 Q. Okay. Doctor, were you retained as an 8 expert epidemiologist in this case? 9 A. I was retained as a gynecologic 10 pathologist. 11 Q. And you are not an epidemiologist; 12 correct? 13 A. I'm not a epidemiologist, but we 14 certainly review epidemiology and critique 15 epidemiology studies on a regular basis in our 16 daily practice. 17 Q. When people ask you what you do for a 18 living, you don't tell them you're an 19 epidemiologist, do you? 20 A. I often have to explain what a 21 pathologist is, so I spend half the time just 22 trying to describe what a pathologist is, so... 23 MR. KLATT: Objection. Nonresponsive. 24 MS. AHERN: Yeah. 25 MR. ROTMAN: She's not done answering</p>	<p style="text-align: right;">Page 216</p> <p>1 Q. You do a full systematic review of the 2 literature, as that term is defined 3 epidemiologically? 4 A. We certainly do when we're doing 5 research, when we're writing papers, but we still 6 do literature searches when we're assigning out 7 cases that are relevant to individual patients. 8 Q. When was the last time you conducted a 9 full systematic review of the literature and a 10 Bradford Hill analysis to opine on causation? 11 A. So, again, this is not something that's 12 completely foreign to me. The legal aspect of it 13 is new to me, but this methodology is not new to 14 me. 15 The last time -- I mean, there was a tobacco 16 case that I worked on, but in my daily practice, 17 again, I'm still looking at epidemiology 18 literature all the time. 19 Q. Well, there is a difference, Doctor, 20 wouldn't you agree, between looking at the 21 epidemiology to inform yourself about a 22 particular issue and doing a systematic review of 23 the literature and a full Bradford Hill analysis 24 to opine on causation? Is there a difference? 25 A. Well, this was a deep dive, so I'll say</p>
<p style="text-align: right;">Page 215</p> <p>1 your question. She's in the middle of an answer. 2 A. So my point is I'm unlikely to describe 3 myself as an epidemiologist when I'm trying to 4 describe what a pathologist does, but that's the 5 big picture. 6 But the real picture is, on a daily basis, 7 we are evaluating epidemiologic data in the 8 literature. 9 BY MS. AHERN: 10 Q. When was the last time you did a 11 systematic review of the literature for the 12 purpose of opining on causation? 13 A. So we review literature -- 14 Q. You. I'm just talking about you. 15 A. Hold on one second. Let me just review 16 the question. I'm way behind here on my -- 17 Well, I do literature searches all the time 18 and looking -- when I'm looking at cases to 19 figure out causation. 20 I've been involved in one other legal case, 21 but it is -- this was the first medical-legal 22 general causation report. 23 But, again, this is all the same methodology 24 that we use in evidence-based medicine and our 25 practice.</p>	<p style="text-align: right;">Page 217</p> <p>1 I was aware of the literature on talcum powder 2 and ovarian cancer before I became involved in 3 this litigation. 4 I will say, you know, it wasn't until they 5 asked me to form my opinion on this that I did a 6 deep dive on the literature again on this 7 particular issue. 8 Again, I've certainly done extensive 9 literature reviews before to, you know -- in 10 research and in practice. 11 Q. But nothing like this? 12 A. It's very similar. 13 MR. ROTMAN: Objection. 14 A. The methodology is very similar to 15 this. It's identical. 16 Q. Doctor, can you point me to -- take a 17 look at Exhibit 2, your CV. 18 Can you point me to something in your CV 19 that demonstrates some specialized knowledge or 20 expertise in epidemiology? A course, a class 21 you've taught? A paper that you've published? A 22 case-control study you've been involved in? 23 Anything that would indicate that you have 24 specialized expertise in epidemiology? 25 A. It's part of our medical training as</p>

<p style="text-align: right;">Page 218</p> <p>1 part of evidence-based medicine.</p> <p>2 I'm trying to find my CV. I'm not sure I</p> <p>3 have it in front of me. Maybe it's under here.</p> <p>4 Well, you're sitting in -- I mean, all of these</p> <p>5 involved epidemiology research.</p> <p>6 MR. ROTMAN: All of what?</p> <p>7 A. I'm sorry. All of these research</p> <p>8 projects start with -- the pathology publications</p> <p>9 start with looking at the literature of</p> <p>10 epidemiology.</p> <p>11 Q. Which ones are you pointing to --</p> <p>12 sorry. Let's look at the peer-reviewed</p> <p>13 publications.</p> <p>14 Is that what you're talking about?</p> <p>15 A. Yes. Sorry.</p> <p>16 Q. So the first publication is Narasimhan,</p> <p>17 "Temperature Induced Interstrand Crosslinks in</p> <p>18 Cisplatin-DNA Adducts Detected by Electrophoresis</p> <p>19 and UV Spectrophotometer."</p> <p>20 That's not an epi study, is it?</p> <p>21 A. Some of these were biology. The one</p> <p>22 that comes to mind when I'm looking at this list</p> <p>23 is the "Yersinia pestis and the plague." That</p> <p>24 was a review article. That was around -- that</p> <p>25 was after the 2001 mailings of the pattern</p>	<p style="text-align: right;">Page 220</p> <p>1 So that was sort of more the review on that.</p> <p>2 Q. Who is S.M. Rollins?</p> <p>3 A. That's my ex-husband.</p> <p>4 Q. What is his specialty?</p> <p>5 A. He's a microbiologist.</p> <p>6 Q. What about Ryan?</p> <p>7 A. He is an infectious disease physician.</p> <p>8 Q. Okay. What portion of "Yersinia pestis</p> <p>9 and the plague" did you draft or did you</p> <p>10 contribute?</p> <p>11 A. I drafted the entire -- I was the lead</p> <p>12 author, and I -- the primary author, and I</p> <p>13 drafted that report.</p> <p>14 Q. Okay. So if we go in there, we're</p> <p>15 going to find you used statistical methods or</p> <p>16 analysis in any way to weigh the evidence and</p> <p>17 conduct a systematic review?</p> <p>18 A. It's definitely a review article. Off</p> <p>19 the top of my head, I don't know if I did a</p> <p>20 statistical analysis, but...</p> <p>21 Q. Would you describe it as more of a</p> <p>22 narrative review of the literature?</p> <p>23 A. A review of the literature. I don't</p> <p>24 know about the word "narrative," but review.</p> <p>25 Q. What about the Grundy paper,</p>
<p style="text-align: right;">Page 219</p> <p>1 substance. And so the literature was very</p> <p>2 interested in Yersinia pestis at the time, and so</p> <p>3 I did a review article on that.</p> <p>4 Q. Was that a systematic review and a</p> <p>5 Bradford Hill analysis?</p> <p>6 A. The Bradford Hill analysis is part of</p> <p>7 evidence-based medicine when you're coming to a</p> <p>8 conclusion. So --</p> <p>9 Q. This isn't a case-control study or a</p> <p>10 prospective cohort study --</p> <p>11 MR. ROTMAN: You're not allowing her to</p> <p>12 finish her answer.</p> <p>13 Q. -- or epidemiology study, is it?</p> <p>14 A. But my general causation opinion is</p> <p>15 very similar to a review article on causation.</p> <p>16 It's a review of the epi data and mechanisms.</p> <p>17 Q. Did you do a full review of the epi</p> <p>18 data and mechanisms on Yersinian plague?</p> <p>19 It's kind of a done deal; right? We already</p> <p>20 know that; isn't that right?</p> <p>21 A. Well, you're still looking at -- you're</p> <p>22 still looking at data. The question is -- the</p> <p>23 question was at the time: Can Yersinia pestis be</p> <p>24 a dangerous weapon of destruction or</p> <p>25 terrorist-type agent?</p>	<p style="text-align: right;">Page 221</p> <p>1 "Specificity of tRNA-mRNA Interactions in</p> <p>2 Bacillus subtilis tyrS Antitermination"?</p> <p>3 Is that an epi study?</p> <p>4 A. No.</p> <p>5 Q. What about the Rollins paper,</p> <p>6 "Diagnostic yield of muscle biopsy in patients</p> <p>7 with clinical evidence of mitochondrial</p> <p>8 cytopathy"?</p> <p>9 Is that an epidemiologic article?</p> <p>10 A. No. That's not an epidemiology</p> <p>11 article, but we --</p> <p>12 Q. Sorry?</p> <p>13 A. It's getting late in the day.</p> <p>14 MR. TISI: Do you need some water?</p> <p>15 THE WITNESS: Sure.</p> <p>16 A. But it's interesting that it actually</p> <p>17 did involve electron microscopy. And when we do</p> <p>18 muscle biopsies for mitochondrial cytopathy, we</p> <p>19 use electron microscopy anyway, regularly.</p> <p>20 MR. KLATT: Objection. Nonresponsive.</p> <p>21 Q. And what about the Rollins</p> <p>22 "Autoimplants and serous borderline tumors of the</p> <p>23 ovary: A clinicopathologic study of 30 cases and</p> <p>24 a process to be distinguished from serous</p> <p>25 adenocarcinoma"?</p>

<p style="text-align: right;">Page 222</p> <p>1 Was that a systematic review of the</p> <p>2 literature, or an epidemiologic study?</p> <p>3 A. There's definitely review of literature</p> <p>4 as part of that study because the question arises</p> <p>5 with autoimplants, sometimes they're misdiagnosed</p> <p>6 as invasive serous.</p> <p>7 So there is definitely literature review for</p> <p>8 that study.</p> <p>9 Q. This would be described as you have it</p> <p>10 in the title, this is a clinicopathologic study?</p> <p>11 A. Correct.</p> <p>12 Q. So you were looking at this as a</p> <p>13 pathologist; correct?</p> <p>14 A. Well, I'm looking at -- I mean, some of</p> <p>15 these were before I was -- the first couple are</p> <p>16 before I was an M.D., but all of the subsequent</p> <p>17 ones I'm looking at as a pathologist.</p> <p>18 Q. What about the Chan study,</p> <p>19 "Clinicopathologic Correlation of Fetal Vessel</p> <p>20 Thrombosis in Mono- and Dichorionic Twin</p> <p>21 Placentas"?</p> <p>22 Is that an epidemiologic study?</p> <p>23 A. That's a clinicopathologic correlation.</p> <p>24 Q. And then the publication with Jonathan</p> <p>25 Hecht, "Endometrial Interepithelial Neoplasia,"</p>	<p style="text-align: right;">Page 224</p> <p>1 are degreed epidemiologists who have been</p> <p>2 designated on behalf of plaintiffs to look at</p> <p>3 these issues; correct?</p> <p>4 A. I'm aware of that now. I didn't know</p> <p>5 who their list was before I submitted my report.</p> <p>6 Q. You've never published -- as we just</p> <p>7 looked through here -- an epidemiologic study, a</p> <p>8 case-control study, or a cohort study?</p> <p>9 A. I have not published; but, again, that</p> <p>10 doesn't -- I mean, it doesn't mean I haven't done</p> <p>11 them. It's just that --</p> <p>12 Q. Have you done them?</p> <p>13 A. They haven't been published. Well,</p> <p>14 again, literature reviews of epidemiology is part</p> <p>15 of our regular practice.</p> <p>16 Q. I'm asking about, like, actual study</p> <p>17 designs.</p> <p>18 Have you conducted a case-control or a</p> <p>19 cohort study?</p> <p>20 A. Not of an epi- --</p> <p>21 Q. Okay.</p> <p>22 A. -- specific design.</p> <p>23 Q. Have you ever taught an epidemiology</p> <p>24 course?</p> <p>25 A. No.</p>
<p style="text-align: right;">Page 223</p> <p>1 is that an epidemiology study?</p> <p>2 A. That was a review of a new terminology</p> <p>3 in endometrial precursor lesions. So that was a</p> <p>4 pathologic -- an anatomic pathology article.</p> <p>5 Q. And then you have the one with Haspel,</p> <p>6 which is "Successful Implementation of a</p> <p>7 Longitudinal, Integrated Pathology Curriculum</p> <p>8 During the Third Year of Medical School"?</p> <p>9 A. That was a medical-education-type</p> <p>10 article.</p> <p>11 Q. Okay. And do you have any proceedings</p> <p>12 of meetings, poster presentations, that were from</p> <p>13 a case-control or a cohort study that you</p> <p>14 conducted?</p> <p>15 A. Let me look. I don't believe these</p> <p>16 poster presentations were case -- well, I mean,</p> <p>17 case-control or cohort epi-type studies.</p> <p>18 Q. Okay. And, Doctor, to be fair, you</p> <p>19 don't have a degree in epidemiology; correct?</p> <p>20 A. I do not have a degree. But, again,</p> <p>21 it's -- epidemiology is a very big part of</p> <p>22 evidence-based medicine and what we practice as</p> <p>23 M.D.s.</p> <p>24 MR. KLATT: Objection. Nonresponsive.</p> <p>25 Q. And, Doctor, you understand that there</p>	<p style="text-align: right;">Page 225</p> <p>1 Q. Do you have any grant funding to</p> <p>2 conduct epidemiologic observational studies?</p> <p>3 A. No.</p> <p>4 Q. Have you ever given any lectures or</p> <p>5 presentations specifically on epidemiology</p> <p>6 methodologies?</p> <p>7 A. That's possible. I'm trying to think.</p> <p>8 It's been a long time. Medical school through</p> <p>9 residency, fellowship, not that I can think of</p> <p>10 off the top of my head.</p> <p>11 Q. Okay. And have you ever designed a</p> <p>12 clinical trial?</p> <p>13 A. I have not designed a clinical trial.</p> <p>14 Q. Have you designed a case-control study?</p> <p>15 A. I have not designed a case-control</p> <p>16 study.</p> <p>17 Q. Have you designed a cohort study?</p> <p>18 A. I have not designed a cohort study;</p> <p>19 but, again, these are -- we can critically</p> <p>20 evaluate. Just because I haven't designed one</p> <p>21 doesn't mean I can't critically evaluate</p> <p>22 case-control studies or cohort studies.</p> <p>23 Q. Doctor, you haven't conducted a</p> <p>24 meta-analysis or a pooled analysis to evaluate</p> <p>25 potential risk factors for any disease, have you?</p>

<p style="text-align: right;">Page 226</p> <p>1 A. No, I haven't.</p> <p>2 Q. Are you qualified to conduct a</p> <p>3 meta-analysis or a pooled analysis?</p> <p>4 A. I'm -- I'm sure I could develop one.</p> <p>5 Q. As we sit here today, are you qualified</p> <p>6 to conduct a meta-analysis or a pooled analysis?</p> <p>7 A. If it was sort of a joint venture, I'm</p> <p>8 sure; but, again, that doesn't mean that I can't</p> <p>9 critically evaluate them, because that's what I</p> <p>10 do on a daily basis.</p> <p>11 Q. Have you authored any paper or</p> <p>12 conducted a study -- well, have you authored any</p> <p>13 paper on the methods of causal interpretation?</p> <p>14 A. Have I authored a paper on the methods</p> <p>15 of causal interpretation?</p> <p>16 I don't believe I've authored. It would be</p> <p>17 on my list.</p> <p>18 Q. Okay. Doctor, I should have asked you</p> <p>19 this when it was in front of you: Do you have a</p> <p>20 copy of that one-page additional materials?</p> <p>21 A. Probably. Let's see.</p> <p>22 Q. Thank you. Maybe I have. Maybe I have</p> <p>23 it too.</p> <p>24 A. Exhibit 17?</p> <p>25 Q. Yes. Yes.</p>	<p style="text-align: right;">Page 228</p> <p>1 asbestos in it, that would certainly add to the</p> <p>2 plausibility of causation.</p> <p>3 Q. If there was not asbestos in talcum</p> <p>4 powder products and there was not fragrance in</p> <p>5 talcum powder products and you were just left</p> <p>6 with the pharmaceutical-grade talc, what would</p> <p>7 your biologic plausibility argument be?</p> <p>8 MR. ROTMAN: Objection.</p> <p>9 Q. In other words, what is your mechanism</p> <p>10 by which pharmaceutical-grade talc would cause</p> <p>11 ovarian cancer?</p> <p>12 MR. ROTMAN: Objection. Are you asking</p> <p>13 about causation or about biological plausibility?</p> <p>14 MS. AHERN: I'm asking --</p> <p>15 MR. ROTMAN: You mixed them.</p> <p>16 MS. AHERN: -- about her mechanism.</p> <p>17 BY MS. AHERN:</p> <p>18 Q. What is your mechanism by which</p> <p>19 pharmaceutical-grade talc would cause ovarian</p> <p>20 cancer?</p> <p>21 A. So there are -- again, most of the</p> <p>22 studies are dealing with talc powder products.</p> <p>23 If we were to say that all that was in there is</p> <p>24 pharmaceutical -- it's completely hypothetical</p> <p>25 because I don't know what's in there -- I still</p>
<p style="text-align: right;">Page 227</p> <p>1 You received a copy of the Longo</p> <p>2 supplemental report; correct?</p> <p>3 A. I did. Yes.</p> <p>4 Q. And it's, what, 404 pages?</p> <p>5 A. That's possible. I don't think I</p> <p>6 looked.</p> <p>7 Q. That was my next question: Did you</p> <p>8 review it?</p> <p>9 A. I did review it. I did skim a lot of</p> <p>10 it because, again, it was additional information</p> <p>11 that was nice to have, but it was after my</p> <p>12 report.</p> <p>13 And, again, my general causation opinion is</p> <p>14 not dependent on asbestos being in the product.</p> <p>15 My general causation opinion is based on whatever</p> <p>16 is in the bottle. So it was interesting</p> <p>17 information to have.</p> <p>18 Q. So your opinions here, it doesn't</p> <p>19 matter for your opinions whether or not there's</p> <p>20 asbestos in talcum powder products; is that your</p> <p>21 testimony?</p> <p>22 A. What I'm saying is my opinion is based</p> <p>23 on whatever is in the talcum powder product's</p> <p>24 bottle. Now, it's up to the jury to decide if</p> <p>25 there's asbestos in it. However, if there is</p>	<p style="text-align: right;">Page 229</p> <p>1 think the mechanisms would be similar where, you</p> <p>2 know, there's evidence that talc can cause</p> <p>3 inflammation, and we know that inflammation is a</p> <p>4 cause of cancer.</p> <p>5 And so I -- and there's also, you know,</p> <p>6 Dr. Cramer talked about anti-MUC-1 antibodies, so</p> <p>7 there's an immune -- plausible immune mechanism,</p> <p>8 so I think all of those are still on the table</p> <p>9 and the hypothetical situation that it's only</p> <p>10 pharmaceutical-grade talc in that bottle.</p> <p>11 But, again, I -- I'm not opining about what</p> <p>12 is in the bottle; I'm just opining about that --</p> <p>13 whatever that product is in that bottle causing</p> <p>14 ovarian cancer.</p> <p>15 Q. Okay. Let's take a look at your expert</p> <p>16 report again, Exhibit 14, if you will.</p> <p>17 Just let me know when you've got it.</p> <p>18 A. Yeah.</p> <p>19 Q. Okay. Doctor, does Exhibit 14, your</p> <p>20 November 15, 2018, expert report, contain all of</p> <p>21 the opinions that you intend to offer as a</p> <p>22 witness in this matter?</p> <p>23 A. I wouldn't box myself in that way.</p> <p>24 There might be questions that I'm asked here</p> <p>25 today or in trial that aren't necessarily in my</p>

<p style="text-align: right;">Page 230</p> <p>1 report.</p> <p>2 Q. Okay. But the opinions that you intend</p> <p>3 to offer, absent somebody asking you to offer</p> <p>4 other opinions, are all outlined or contained</p> <p>5 within Exhibit 14, your report; is that correct?</p> <p>6 A. Again, I wouldn't want to say "all." I</p> <p>7 wouldn't want to limit myself. There's always</p> <p>8 the possibility that something else will come up,</p> <p>9 and I even have a thing that additional</p> <p>10 information may come up.</p> <p>11 Q. Okay. As we sit here today, do you</p> <p>12 understand that this is our opportunity to ask</p> <p>13 you about the opinions in your report, and we</p> <p>14 have the day to do it?</p> <p>15 Do you understand that?</p> <p>16 A. I understand.</p> <p>17 Q. Okay. So to the extent that you think</p> <p>18 you're going to offer additional opinions or</p> <p>19 different opinions, we need to know that today.</p> <p>20 I understand that if something comes up two</p> <p>21 weeks from now and it's additional information,</p> <p>22 you might supplement your report.</p> <p>23 But as of today, as we sit here today, is</p> <p>24 this report an accurate reflection of the</p> <p>25 opinions that you have formed and that you intend</p>	<p style="text-align: right;">Page 232</p> <p>1 probably have within them all the references to</p> <p>2 your report. Other than those and what you</p> <p>3 brought with you today, is there anything else</p> <p>4 related to your work on your report that you have</p> <p>5 in your possession that you haven't been able to</p> <p>6 bring with you today?</p> <p>7 A. Not that I'm aware of. I've tried to</p> <p>8 be very complete in my list of what I reviewed.</p> <p>9 It's possible -- again, it's possible there are a</p> <p>10 couple of things that might have been left off,</p> <p>11 but I tried to be as complete as possible.</p> <p>12 Q. Okay. And you mentioned earlier you</p> <p>13 had done some work on the pathogenesis of ovarian</p> <p>14 cancer.</p> <p>15 Did you have any articles or publications</p> <p>16 that are related to that work that are not</p> <p>17 referenced in your report?</p> <p>18 A. I believe they should be in the list.</p> <p>19 They should be included in the list that you</p> <p>20 have.</p> <p>21 Q. The one from -- your initial report?</p> <p>22 A. Taken all together. Taken all</p> <p>23 together. So that, probably, is more -- the</p> <p>24 January 4th one would probably be some of those.</p> <p>25 And then I can't remember what's on that one</p>
<p style="text-align: right;">Page 231</p> <p>1 to offer in this case?</p> <p>2 A. I would say it's an accurate reflection</p> <p>3 of the opinions I have formed with the exception</p> <p>4 of anything that might be asked that is not in</p> <p>5 the report; but yes.</p> <p>6 Q. All right. All right.</p> <p>7 And as we sit here today, is your report</p> <p>8 complete?</p> <p>9 A. Well, it's signed and turned in, so --</p> <p>10 Q. Do you, as the expert designated in</p> <p>11 this case, Sarah Kane, do you consider your</p> <p>12 report to be complete as we sit here today?</p> <p>13 A. Yes.</p> <p>14 MR. ROTMAN: Off the record.</p> <p>15 (Discussion off the record.)</p> <p>16 THE VIDEOGRAPHER: Off the record,</p> <p>17 3:24 p.m.</p> <p>18 (A recess was taken.)</p> <p>19 THE VIDEOGRAPHER: Here begins Media</p> <p>20 No. 5 in today's deposition of Sarah Kane, M.D.</p> <p>21 Back on the record, 3:39 p.m.</p> <p>22 BY MS. AHERN:</p> <p>23 Q. Okay. Dr. Kane, we were talking about</p> <p>24 your report. Just some basic housekeeping first.</p> <p>25 We have the four boxes back here which</p>	<p style="text-align: right;">Page 233</p> <p>1 that you just got, but if there's a couple on</p> <p>2 there.</p> <p>3 But I would think if they weren't cited in</p> <p>4 the report, the majority of those should be in</p> <p>5 the January 4th list.</p> <p>6 Q. Okay. And those would pertain to the</p> <p>7 various histologic categorizations of ovarian</p> <p>8 cancer; what is known about etiology.</p> <p>9 Is that kind of the gist of the information</p> <p>10 that you researched?</p> <p>11 A. Yes. Yes. That was certainly part of</p> <p>12 it.</p> <p>13 Q. And were there other parts to that?</p> <p>14 THE WITNESS: Is that -- I don't know</p> <p>15 if --</p> <p>16 MR. ROTMAN: Yeah. You can say what</p> <p>17 work you did.</p> <p>18 A. There was -- so a good bit of it was</p> <p>19 sort of background information on the pathologic</p> <p>20 diagnosis of ovarian cancer and different, as you</p> <p>21 said, different subtypes.</p> <p>22 There was -- I'm trying to remember -- it</p> <p>23 was so long ago -- what some of the -- I believe</p> <p>24 there was a little bit more on inflammation, but</p> <p>25 I can't say for sure.</p>

<p style="text-align: right;">Page 234</p> <p>1 BY MS. AHERN: 2 Q. And would that have been just related 3 to ovarian cancer pathogenesis? 4 A. Yes. Yes. 5 Q. And you think that all of the 6 publications that you found, identified, reviewed 7 in relation to that work are identified in one of 8 the lists or across several lists? 9 A. I'm hoping that across all of the 10 lists, that encompasses the vast majority, if not 11 all. But let's just keep it at vast majority. 12 And, of course, you know, I'm a gynecologic 13 pathologist, so I read tons of other stuff that, 14 you know, is just my background knowledge that 15 I'm not going to put on these lists. So I can't 16 say it's all-inclusive; but, again, I tried. 17 Q. Understood. Understood. 18 And you've now seen at least one report from 19 Dr. Robert Kurman; correct? 20 A. That's correct. That was an individual 21 causation report, though. So... 22 Q. And he had a very large background 23 section on ovarian cancer pathogenesis; correct? 24 A. To be honest with you, I sort of 25 skimmed it, but I do remember seeing a section on</p>	<p style="text-align: right;">Page 236</p> <p>1 Exhibit 14, your expert report, are they solely 2 the product of your own work? 3 A. Yes. I wrote the report. Certainly, 4 again, there were drafts that went back and 5 forth. There may have been suggestions from 6 attorneys where language was -- that I accepted 7 into my report; but yes. 8 Q. Okay. You didn't borrow language from 9 other experts or from other publications and then 10 not quote that in your report? 11 A. I certainly tried not to. No. I 12 certainly cited anything that I -- I tried to 13 cite everything that I referenced -- 14 Q. Okay. 15 A. -- to the best of my ability. 16 You know, again, I was taking the notes as I 17 wrote, so it's plausible there might be 18 something, but I was very cognizant of trying not 19 to -- trying to cite everything that I was 20 referencing. 21 Q. And in reaching your opinions, was it 22 important to you that you review the data in a 23 fair and objective way? 24 A. Yes. I think it's always important to 25 review data in a fair and objective way.</p>
<p style="text-align: right;">Page 235</p> <p>1 that. Yes. 2 Q. Okay. Did you skim the section that 3 was case-specific? 4 A. No. Mostly the background since I 5 already know that stuff. 6 Q. Okay. And is the stuff that was in his 7 background section similar to the research that 8 you did? 9 A. I would say yes. If I am remembering 10 accurately, it was similar. I wouldn't say 11 identical, but similar. 12 Q. Okay. And did anyone other than your 13 attorneys assist you in preparing the report? 14 A. No. 15 Q. And you said earlier, I think, that you 16 didn't consult with any of the other experts in 17 the MDL litigation in forming your opinions or 18 preparing your report? 19 A. That's correct. 20 Q. And you didn't review any draft reports 21 from any other experts in this litigation? 22 A. No. The only time I saw their reports 23 was after we had all turned them in to the court. 24 Q. Okay. And are all of the words, the 25 ideas, the analysis that's contained in</p>	<p style="text-align: right;">Page 237</p> <p>1 Q. I know. It's kind of a basic question. 2 When you were doing your literature reviews 3 and searches, were you looking both for papers or 4 data that supported talc and ovarian cancer 5 connection as well as for data and literature 6 that did not or that -- well, that did not 7 support? 8 A. When I was doing my literature search, 9 I was looking for any data that spoke to talcum 10 powder products and ovarian cancer. I was really 11 trying to cast as wide a net as possible to get 12 as much data as I could. 13 Now, certainly, there are limitations when 14 you're doing searches. It's possible there are 15 studies that I missed; but when I was retrieving 16 studies, reading them, I would also reference 17 their references as a sort of cross-check. So I 18 tried to be as complete as I could. 19 Q. So when you were reading someone else's 20 work and they referenced an article as the basis 21 for synthesis or the statement in their paper, 22 did you then go and review the underlying 23 reference as well? 24 A. Yes. I pulled up those references. 25 Q. Okay. And you reviewed those as well?</p>

<p style="text-align: right;">Page 238</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And you mentioned on Page 4 of</p> <p>3 your report that your interest in talc and</p> <p>4 ovarian cancer began during your training, your</p> <p>5 fellowship training, at Mass General; is that</p> <p>6 right?</p> <p>7 A. I became aware of it. I mean, both</p> <p>8 Dr. Scully and Dr. Bell were still there at my</p> <p>9 time of training, and Dr. Scully was a coauthor</p> <p>10 on Cramer's first 1982 paper.</p> <p>11 And then Dr. Bell was a coauthor in one of</p> <p>12 the subsequent -- I think his 1992 paper with</p> <p>13 Harlow.</p> <p>14 So I was certainly aware of literature on</p> <p>15 talcum powder and ovarian cancer.</p> <p>16 Q. And neither one of them published</p> <p>17 anything else on talc; is that correct?</p> <p>18 A. I believe those were the only two that</p> <p>19 they were on. That's correct.</p> <p>20 Q. And did you understand that the role</p> <p>21 that Dr. Scully played on Dr. Cramer's first</p> <p>22 publication was simply that of pathologist and</p> <p>23 determining or confirming the diagnosis of the</p> <p>24 samples that were being studied?</p> <p>25 A. I was aware that he did a pathologic</p>	<p style="text-align: right;">Page 240</p> <p>1 I know we talked about the Nurses' Health Study.</p> <p>2 That's funny, though, I actually did talk --</p> <p>3 I saw Jonathan last night, so it's kind of funny</p> <p>4 timing. But anyway...</p> <p>5 Q. Have you talked to Dr. Hecht since</p> <p>6 then, since you first discussed with him the</p> <p>7 Nurses' Health Study?</p> <p>8 Have you spoken with him on talc and ovarian</p> <p>9 cancer?</p> <p>10 A. Yes. I saw him last night. We went</p> <p>11 out for a drink.</p> <p>12 Q. Did he give you any opinions on what he</p> <p>13 thought about talc and ovarian cancer?</p> <p>14 A. He told me that he had met with defense</p> <p>15 counsel at one point; did not want to do medical</p> <p>16 expert witness work but did a brief sort of</p> <p>17 intro, I guess, overview for the defense.</p> <p>18 Q. Did he tell you what his personal or</p> <p>19 his professional opinion was on whether or not</p> <p>20 talc causes ovarian cancer?</p> <p>21 A. Yes. He thought that -- so I'll say in</p> <p>22 my report, I did not spend a lot of time on</p> <p>23 migration because in the gynecologic world, it's</p> <p>24 widely accepted that migration happens. He told</p> <p>25 me that he specifically told the defense counsel</p>
<p style="text-align: right;">Page 239</p> <p>1 review of the case.</p> <p>2 Q. Okay. Did you ever have an opportunity</p> <p>3 to talk to Dr. Scully about talc and ovarian</p> <p>4 cancer?</p> <p>5 A. I believe my conversations were -- my</p> <p>6 memory is -- this is 20 years ago now -- it's</p> <p>7 possible, but probably with Dr. Bell, more. I</p> <p>8 interacted more with Dr. Bell than Dr. Scully.</p> <p>9 Dr. Scully was semiretired at the time. He</p> <p>10 would come in for half the day, but that was</p> <p>11 usually when I was with other attendings. But I</p> <p>12 did spend a significant time with Dr. Bell, and I</p> <p>13 do remember being aware of that literature.</p> <p>14 Now, if you're going to ask me the specific</p> <p>15 conversation, I probably can't prompt that at the</p> <p>16 moment.</p> <p>17 I was also, when I was at Beth Israel</p> <p>18 Deaconess, my colleague Jonathan Hecht is there.</p> <p>19 And I was aware he was doing work on the Nurses'</p> <p>20 Health Study.</p> <p>21 We didn't -- I can't remember if we really</p> <p>22 talked about talc at that point because the Gates</p> <p>23 2010 paper that he was doing, talc was a very</p> <p>24 small -- it was almost, like, a side comment in</p> <p>25 that report. But I think we had talked about --</p>	<p style="text-align: right;">Page 241</p> <p>1 he met with not to use migration because it's</p> <p>2 widely accepted that it occurs.</p> <p>3 We did talk about the Nurses' Health paper.</p> <p>4 He said that the data set was very small, it was</p> <p>5 very difficult with classification, and that</p> <p>6 that -- there just really wasn't a lot of data in</p> <p>7 that 2010 study.</p> <p>8 And he thinks that it is plausible for</p> <p>9 talcum powder to cause ovarian cancer.</p> <p>10 Q. Have you spoken to any other</p> <p>11 pathologist or colleagues about talc and ovarian</p> <p>12 cancer?</p> <p>13 A. I have talked to my coworkers about it</p> <p>14 because -- as a conflict-of-interest notification</p> <p>15 for our group and for our hospital, Partners</p> <p>16 Healthcare, and I discussed my findings with my</p> <p>17 partners.</p> <p>18 And I've also talked about it at</p> <p>19 multidisciplinary conferences; recently at, for</p> <p>20 example, at a thoracic conference. There were</p> <p>21 gyn oncs there and radiologists and rad onc</p> <p>22 people there.</p> <p>23 Q. And you talked to them specifically</p> <p>24 about talc and ovarian cancer?</p> <p>25 A. So I told them about my work on it and</p>

<p style="text-align: right;">Page 242</p> <p>1 the research that I had done, and I was asking 2 them -- it was a thoracic conference, so I was 3 curious if any of them had asked any of their 4 mesothelioma patients that didn't have 5 nonasbestos exposure if they've ever asked them 6 if they'd had talc exposure. 7 And they said no, they hadn't really done 8 it, they hadn't thought about it, but maybe it 9 was something that they should be asking. 10 Q. And, by the way, what were the 11 circumstances under which you and Dr. Hecht had 12 dinner the other night? 13 A. His birthday is coming up. We're still 14 friends, so it was one of these -- I actually 15 stayed in a hotel last night because it took me 16 an hour and a half to drive from Topsfield 17 yesterday morning, and I didn't want to be 18 worried about traffic. So I decided to stay in a 19 hotel last night. His birthday is coming up, so 20 I said, "Let's just grab a drink." 21 Q. You mentioned while you were at Mass 22 General, the fellowship director for your program 23 was Robert Young; correct? 24 A. Yes. 25 Q. Is he someone that you look up to as a</p>	<p style="text-align: right;">Page 244</p> <p>1 Dr. Scully retired; is that right? 2 A. Yes. He inherited his consult service. 3 So it's a separate service from our regular 4 clinical work. So it's pathologists from all 5 over the country or even world that have 6 difficult cases, they will send as a specific 7 private consult to -- it was Dr. Scully, and now 8 it's Dr. Young. 9 Q. Okay. When you were first contacted by 10 the plaintiffs' counsel back in 2017, what were 11 your opinions regarding talc and ovarian cancer 12 at that point? 13 A. First contacted? When I was first 14 contacted, I was aware of the literature, 15 certainly. I hadn't come to a strong opinion one 16 way or the other. In fact, I'd probably say I 17 was aware that the epi data had been relatively 18 consistent. That was kind of all I knew about it 19 until I did my sort of deep dive into the 20 literature for my general causation opinion. 21 Q. So as a pathologist, you never had a 22 particular interest in pursuing additional 23 research in the area -- 24 MR. ROTMAN: Objection. 25 Q. -- of talc and ovarian cancer?</p>
<p style="text-align: right;">Page 243</p> <p>1 pathologist? 2 A. Yes. He's very well-respected. 3 Q. By the way, who do you send second 4 opinion consults to when you have a difficult 5 case? 6 A. We have a relationship with Mass 7 General, so I'll occasionally send -- if I need 8 another set of eyes on, I'll send it to either -- 9 it's sort of their gyn pathology group in 10 general, so it might be Dr. Young. It might be 11 Esther Oliva. Those are the two that I would say 12 most frequently would receive any consults from 13 our group for gyn path. 14 Q. Have you ever spoken with Dr. Young 15 about talc and ovarian cancer? 16 A. It's possible. I haven't recently. He 17 and I aren't in regular communication, so I 18 certainly wouldn't have talked to him -- I don't 19 know if I've talked to him since starting this. 20 It's more of a professional-type 21 relationship, so I don't know if it would have 22 come up recently. But it's possible in training, 23 but I don't remember specifically. 24 Q. And Robin Young inherited all of 25 Dr. Scully's case files in his office when</p>	<p style="text-align: right;">Page 245</p> <p>1 A. Well, there's certainly a lot of things 2 to study in gynecologic pathology. And so I 3 hadn't decided to take that -- to do that study 4 at the time that I was contacted by counsel. 5 That's not to say I never would have or I never 6 would have thought about it, but I hadn't at the 7 time. 8 Q. Okay. In your report on Page 4, you 9 say that you've maintained a professional 10 interest -- "since your fellowship, you've 11 maintained a professional interest and have 12 continued to monitor developments in the science 13 regarding talcum powder exposure and ovarian 14 cancer, and it has been the subject of 15 professional discussions predating the 16 litigation." 17 So what sort of professional discussions 18 about talc and ovarian cancer did you have before 19 the plaintiffs retained you? 20 A. So, again, I was aware of the 21 literature. And I knew -- I saw some of the 22 newer epi data come out. I had had conversations 23 with Dr. Bell that I remember specifically; 24 again, with Jonathan. I knew he was working on 25 that Nurses' Health. We certainly talked about</p>

<p style="text-align: right;">Page 246</p> <p>1 that study at some point.</p> <p>2 But, you know, I was certainly aware of the</p> <p>3 literature as it came out.</p> <p>4 Q. And you call it a "professional</p> <p>5 interest."</p> <p>6 Did you take -- other than just reviewing</p> <p>7 the literature, did you do anything</p> <p>8 professionally to either advance your knowledge</p> <p>9 or other people's knowledge about this potential</p> <p>10 association?</p> <p>11 A. Not -- I mean, not at the time. I</p> <p>12 think "professional interest" in my mind, you</p> <p>13 know, means being aware of what's going on in the</p> <p>14 literature. Again, that doesn't necessarily mean</p> <p>15 an in-depth review of everything but being</p> <p>16 generally aware of it.</p> <p>17 Q. Would you say that since you first</p> <p>18 learned about this in your fellowship and were</p> <p>19 interested in the topic, did it influence the way</p> <p>20 you looked at gynecologic cases as a professional</p> <p>21 pathologist?</p> <p>22 A. Yeah. It's not really routine practice</p> <p>23 to use polarized light microscopy in gynecologic</p> <p>24 pathology. It's just -- we use it more commonly</p> <p>25 for breast cases, so...</p>	<p style="text-align: right;">Page 248</p> <p>1 in the report.</p> <p>2 Q. Okay. And the first opinion is that</p> <p>3 talc can migrate to the ovaries through the</p> <p>4 genital tract through the lymphatic system and</p> <p>5 through inhalation.</p> <p>6 Is that an accurate summary of your first</p> <p>7 opinion or set of opinions?</p> <p>8 (reading from document)</p> <p>9 A. Yes. The talcum powder products can</p> <p>10 reach the ovaries; that they can be transported</p> <p>11 through the lymphatic system; and there is</p> <p>12 evidence that it can be inhaled as well with</p> <p>13 transport to the ovaries.</p> <p>14 Q. And the second opinion in the case or</p> <p>15 second set of opinions is that talc causes</p> <p>16 chronic inflammation in the ovaries, causes</p> <p>17 increased oxidative stress in the ovaries, and</p> <p>18 causes immunosuppression.</p> <p>19 Is that an accurate summary of your</p> <p>20 mechanism?</p> <p>21 A. Well, if you're going to read it word</p> <p>22 for word, it's "Once reaching the ovaries, talcum</p> <p>23 powder products can cause chronic inflammation,</p> <p>24 can increase oxidative stress, and can reduce</p> <p>25 immune response. These are biologically</p>
<p style="text-align: right;">Page 247</p> <p>1 And also, you know, even if we found</p> <p>2 birefringent particles and granulomas or -- in</p> <p>3 the tissue, it wouldn't necessarily mean that</p> <p>4 they're talc unless you do subsequent studies.</p> <p>5 So I wouldn't say it changed my daily</p> <p>6 practice in diagnosing tumors.</p> <p>7 Q. Okay. Doctor, if you can turn to</p> <p>8 Page 4 and 5 of your report.</p> <p>9 Is this where you set out a summary of your</p> <p>10 opinions?</p> <p>11 A. Yes. This is.</p> <p>12 Q. Under Heading 2, Page 4, "General</p> <p>13 causation opinions."</p> <p>14 A. Okay.</p> <p>15 Q. And you list, it looks like, five</p> <p>16 specific opinions; is that correct?</p> <p>17 A. I see where you are. Yes.</p> <p>18 Q. And are those -- again, are those all</p> <p>19 the opinions that you have that you intend to</p> <p>20 offer in this case?</p> <p>21 MR. ROTMAN: Objection.</p> <p>22 A. Same answer as before. Again, there</p> <p>23 might be something that comes up today or at</p> <p>24 trial that I'm asked that I, you know, didn't put</p> <p>25 in this report. But I tried to be as -- complete</p>	<p style="text-align: right;">Page 249</p> <p>1 plausible and likely mechanisms for ovarian</p> <p>2 cancer development and progression."</p> <p>3 Q. Okay. When you say "reduce the immune</p> <p>4 response," is that essentially discussing, like,</p> <p>5 an immunosuppressive effect?</p> <p>6 A. That's referencing the MUC-1 antibody</p> <p>7 paper that Cramer published in 2005.</p> <p>8 Q. Are you aware that Dr. Cramer himself</p> <p>9 has disclaimed that theory as a "hypothesis</p> <p>10 that's not ready for prime time"? I believe</p> <p>11 those were his words, "prime time."</p> <p>12 A. I don't know where you saw those words.</p> <p>13 Q. His testimony in the litigation.</p> <p>14 A. Okay. I don't believe I saw his</p> <p>15 testimony in the litigation. But, again, it's</p> <p>16 not -- I'm not seeing it as something that needs</p> <p>17 to be proven. I'm looking at it as a</p> <p>18 plausibility that, you know, it's a plausible</p> <p>19 mechanism. If it's not proven, it doesn't really</p> <p>20 change the fact that it's plausible.</p> <p>21 Q. So are you building -- so is your</p> <p>22 plausibility opinion independent of whether or</p> <p>23 not the basis for that opinion is proven?</p> <p>24 MR. ROTMAN: Objection.</p> <p>25 Q. In other words, are you -- do you have</p>

<p style="text-align: right;">Page 250</p> <p>1 a plausibility opinion that's based on a bunch of 2 other potential or plausible mechanisms? 3 MR. ROTMAN: Objection. 4 A. Right. 5 MR. ROTMAN: I just objected, but you 6 can answer. If you can understand the question, 7 you can answer it. 8 A. Well, I think -- I think they're all 9 somewhat interrelated. 10 I think there's the chronic inflammation. 11 There's the immune response. Those are plausible 12 mechanisms for ovarian cancer. 13 And the Bradford Hill guidelines, you don't 14 have to prove -- prove mechanism in order to have 15 causation. We have plenty of -- again, plenty of 16 examples of that in prior diseases, like smoking 17 and lung cancer. And even certain drugs, they 18 don't know the mechanism of action, very common 19 drugs like lithium, for example, or metformin. 20 So you don't need to prove mechanism in 21 order for it to be an important part of a 22 causation because it's part of the plausibility 23 component. 24 Q. Do any of the bases on which you -- any 25 of the bases that you use to support plausibility</p>	<p style="text-align: right;">Page 252</p> <p>1 reaching the ovaries. 2 So -- and, again, it's widely accepted in 3 the gynecologic community that migration occurs. 4 In fact, endometriosis, we really -- the evidence 5 is that endometriosis is caused by retrograde 6 menstruation of endometrium. 7 So there's a substantial amount of evidence 8 and widely accepted that migration occurs. 9 And I'm aware of studies that didn't find 10 migration, but I think, you know, those few 11 negative studies don't cancel out the positive 12 studies. 13 And, you know, certainly, looking for 14 migrated particles is very difficult. You know, 15 again, we're talking about dose. How much do you 16 inject to get there? 17 And so I think the positive studies are 18 compelling, and it's widely accepted that 19 migration occurs. 20 (Article entitled "Presence of 21 Talc in Pelvic Lymph Nodes of a Woman with 22 Ovarian Cancer and Long-Term Genital 23 Exposure to Cosmetic Talc" marked Exhibit 24 19.) 25</p>
<p style="text-align: right;">Page 251</p> <p>1 for talc and ovarian cancer, do any of them have 2 to be proven or established? 3 MR. ROTMAN: Objection. 4 A. I think it's important to have evidence 5 to support it. There may be evidence that 6 refutes it as well, but you're sort of looking 7 at -- you're balancing the weight of it. 8 And the plausibility, a plausible mechanism, 9 now, is that always going to be probable or 10 definite? No. It's plausible. 11 In this case, I think it's a compelling 12 mechanism, chronic inflammation, because, again, 13 we know that talcum powder can reach the ovaries, 14 and we know that it can cause chronic 15 inflammation, and we know chronic inflammation is 16 implicated in cancer. 17 So I think it's a high degree of 18 plausibility in that case. 19 Q. So when you mention that you know that 20 talc can reach the ovaries, are you referring to, 21 for example, the Heller study? 22 A. So Heller found talc in women's 23 ovaries. Yes. Cramer found talc in pelvic lymph 24 nodes. We have other animal and human studies of 25 talc or particulates similar in size to talc</p>	<p style="text-align: right;">Page 253</p> <p>1 BY MS. AHERN: 2 Q. Doctor, I'm handing you what's been 3 marked as Exhibit 19 to your deposition. 4 A. Okay. 5 MR. TISI: Thank you. 6 MS. AHERN: You're welcome. 7 Q. Exhibit 19 is an article drafted by 8 Dr. Dan Cramer, the "Presence of talc in pelvic 9 lymph nodes of a woman with ovarian cancer and 10 long-term genital exposure to cosmetic talc." 11 Is this a paper that you were referring to a 12 few minutes ago? 13 A. The 2005, yes. 14 Q. This is 2007. 15 A. I'm sorry. Did I say 2005? Yes. This 16 is the paper, anyway. 17 Q. And the authors are Dan Cramer and Bill 18 Welch, Ross Berkowitz, and John Godleski. 19 Do you see that? 20 A. Yes. 21 Q. And three of those individuals have 22 been disclosed as plaintiffs' experts in the talc 23 litigation. 24 Were you aware of that? 25 A. I was not aware of Bill Welch. I knew</p>

<p style="text-align: right;">Page 254</p> <p>1 after -- at some point, I was aware that 2 Dr. Cramer and Dr. Godleski was. I don't believe 3 I was aware of that at the beginning of my 4 research, but I became aware of that. Yes. 5 Q. Okay. Are you aware that Dr. Welch has 6 been designated in maybe three cases and given 7 testimony in those cases? 8 A. Again, I was not aware that Bill Welch 9 had been retained. 10 Q. Are you aware that Dr. Welch has run 11 the pathology portion of Dr. Cramer's study 12 program for 40 years? 13 A. I'm aware who Dr. Welch is, and I've 14 certainly seen his name on papers. But now 15 his -- his role in these studies specifically, I 16 don't know if I can speak to other than he's 17 involved. 18 Q. He's testified that his only role was 19 in identifying the types of tumors involved in 20 the study to keep people honest. 21 Are you aware that Dr. Welch has repeatedly 22 refused to give -- refused to give a causation 23 opinion like you're giving today? 24 A. I'm not aware of Dr. Welch's opinions. 25 I didn't know that he was an expert, so I</p>	<p style="text-align: right;">Page 256</p> <p>1 A. I'm sorry. Where are you now? 2 Q. Same sentence. He just finishes it 3 with "Many subsequent studies found -- 4 A. Okay. 5 Q. -- "talc use to increase the risk for 6 ovarian cancer." 7 But he just cites himself again from 1982; 8 correct? 9 A. Sorry? 10 Q. The only cite he provides for that 11 statement is his own study from 1982? 12 A. Oh, the one -- the No. 1? 13 Q. Mm-hmm. 14 A. Yes. That's his 1999, it says. 1999. 15 Q. Okay. Sorry about that. You're right. 16 And then he says, "However, the causality of 17 the relationship has been challenged for several 18 reasons." 19 Do you see that? 20 A. I do. 21 Q. And he says, "First, the association is 22 a relatively weak one; i.e., summary relative 23 risk of approximately 1.3." 24 Do you agree that a summary relative risk of 25 1.3 is a weak association?</p>
<p style="text-align: right;">Page 255</p> <p>1 wouldn't have reviewed any of that testimony. 2 Q. Okay. You weren't provided with any of 3 his testimony or his reports in the litigation? 4 A. No. I was not aware that he was a 5 medical expert witness. 6 Q. Okay. Do you see under the 7 "Background" section here, it says, "Although 8 epidemiologic studies suggest talc may increase 9 ovarian cancer risk, there is no proof that talc 10 used externally reaches the pelvis"? 11 A. That's what it says. 12 Q. Are then if you look down in the -- I'm 13 sorry. I'm sorry. 14 If you look down in the first paragraph, he 15 mentions, "An epidemiologic association between 16 the use of cosmetic talc and genital hygiene and 17 ovarian cancer was first described in 1982." 18 That's Cramer citing Cramer; isn't it? 19 A. Let's see. Let me double-check. I'm 20 assuming because it's 1982. But let me 21 double-check. Or -- yeah. It's 1999. He's 22 referencing his 1999 paper. 23 Q. And he says, "And the many subsequent 24 studies found talc use to increase the risk for 25 ovarian cancer."</p>	<p style="text-align: right;">Page 257</p> <p>1 A. I've seen "weak" or "moderate" used to 2 describe a 1.3, but that doesn't mean it's not a 3 significant one, especially in a rare disease 4 like ovarian cancer. 5 MS. AHERN: Objection to the 6 nonresponsive portion. 7 Q. But I agree it's been described as 8 "weak," at least here by Dr. Cramer? 9 A. That's -- the sentence says, "First, 10 the association is a relatively weak one; i.e., 11 summary relative risk of approximately 1.3." 12 Q. And he says, "Second, there's no clear 13 increase in risk with duration of use." 14 Do you agree with that, as of 2007, there 15 was no clear dose-response in the studies that 16 looked at talc and ovarian cancer? 17 A. I think there was evidence of a 18 dose-response by 2007. 19 Q. So do you disagree with Dr. Cramer's 20 statement in the 2007 publication that as of that 21 time, there was no clear increase in risk with 22 duration of use in most studies? 23 A. I wouldn't necessarily phrase it that 24 way: There's no clear increased risk. I think, 25 again, there isn't a lot of data, but what data</p>

<p style="text-align: right;">Page 258</p> <p>1 there was -- I believe at that time, I'm trying 2 to think if I was in 2007 -- would be evidence 3 that there was a dose-response. 4 Q. And which papers, prior to 2007, did 5 they find dose-response that was clear? 6 A. I would have to look back. 7 Okay. So I tried to do this in chronologic 8 order. 9 Q. What page are you on? 10 A. I'm looking at 16. 11 Q. Page 16 of Exhibit 14? 12 A. Yes. 13 Q. Okay. Were -- 14 A. I'm just trying to refresh my memory. 15 So Harlow's -- let's see -- 1992 study was, 16 it looks like, the first one that I have listed 17 that had a dose-response -- evaluated for 18 dose-response. 19 They both -- let's see. The confidence 20 intervals all included the null. Life- -- so 21 what I wrote here -- this is Page 18 -- "lifetime 22 application ORs when compared to control women 23 with no perineal talc exposure were 1.3, 4 less 24 than 1,000, with a confidence interval of 0.7 to 25 2.7; 1.5 for 1,000 to 10,000 with a confidence</p>	<p style="text-align: right;">Page 260</p> <p>1 2.4. 2 And for greater than 10,000, we're looking 3 at 1.0 to 3.0. 4 Q. And when they just adjusted -- when 5 they excluded -- when they looked at lifetime 6 talc applications and ovarian cancer after 7 excluding use following hysterectomy or tubal 8 ligation, they found no evidence of an 9 exposure-response relationship, didn't they? 10 A. Are you looking at the actual paper? 11 Q. Do you need it? 12 A. If you're asking me questions about it. 13 Q. Yeah. That wasn't in your report -- or 14 is it? 15 MR. ROTMAN: What is the "it" referring 16 to? 17 Q. That particular finding is not in her 18 report on dose-response from Harlow in 1992? 19 A. Well, yeah. Let me look at the -- 20 MS. AHERN: Sure. 21 (Article entitled "Perineal 22 Exposure to Talc and Ovarian Cancer Risk" 23 marked Exhibit 20.) 24 MS. AHERN: I'll mark as Exhibit 20 to 25 your deposition "Perineal Exposure to Talc and</p>
<p style="text-align: right;">Page 259</p> <p>1 interval of 0.9 to 2.4; and 1.8 for greater than 2 10,000 with the confidence interval of 1.0 to 3 3.0. 4 And then I also -- yeah. So that's after 5 2007, the Terry and the Lou studies. 6 Q. You're looking at Harlow 1992? 7 A. Yes. That's the paragraph I'm looking 8 at. 9 Q. And Harlow 1992 found a 10 nonstatistically significant increased risk; is 11 that correct? 12 A. So the confidence intervals included 13 the null. So, yeah, it was not statistically 14 significant. I'm not sure -- I don't have the 15 numbers here, though, of how many they had 16 dose-response data on, which would -- which might 17 increase the interval. 18 In fact, if you look at the confidence 19 intervals, they're pretty wide, trending toward 20 higher. 21 Q. What are the confidence intervals 22 you're looking at? 23 A. For less than 1,000 lifetime 24 applications, we're looking at 0.7 to 2.7. 25 For 1,000 to 10,000, we're looking at 0.9 to</p>	<p style="text-align: right;">Page 261</p> <p>1 Ovarian Cancer Risk" by Harlow, 1992. That's my 2 only copy. Sorry. 3 MR. ROTMAN: Exhibit 20. 4 A. Okay. So, I'm sorry, where are you 5 looking? 6 Q. Let me find it. Take your time, if you 7 need to. I'm trying to find my copy. 8 Okay. If you look at Table 3, "Estimated 9 total lifetime perineal applications of talc 10 containing powders and cases and controls." 11 A. Okay. I see Table 3. 12 MR. ROTMAN: Is there a question? 13 MS. AHERN: She asked to see the study. 14 I asked her to confirm that once they excluded 15 cases after hysterectomy or tubal ligation, there 16 was no exposure-response relationship. 17 A. These look to be similar -- oh, I see. 18 Okay. Total applications. 19 Well, if you actually look at the numbers, 20 the ones above, which are, I believe, what I 21 quoted in my report, so under "Total 22 applications." 23 And then you're asking me about applications 24 excluding use after hysterectomy or tubal 25 ligation?</p>

<p style="text-align: right;">Page 262</p> <p>1 BY MS. AHERN: 2 Q. Mm-hmm. 3 A. What was your question about it? I'm 4 sorry. 5 Q. There's no statistically significant 6 dose-response relationship with lifetime 7 application? 8 A. So the confidence intervals are 9 somewhat similar, but -- are somewhat similar, it 10 looks like, to the top. 11 Q. There's no statistically significant 12 dose-response relationship, is there? 13 A. They all include the null. That's 14 correct. But, again, they're trending high. 15 Q. But if they include the null, then it's 16 consistent with the null hypothesis that there's 17 no association; isn't that true? 18 MR. ROTMAN: Objection. 19 A. It's possible. The null hypothesis is 20 included in "Possibilities." 21 Q. It also basically means you can't 22 exclude chance as a reason for the findings; 23 correct? 24 A. Again, it's possible. I would say it's 25 trending higher, but it does include the null</p>	<p style="text-align: right;">Page 264</p> <p>1 dose-response? 2 A. Well, I state in my report what the 3 confidence intervals are. So certainly, I'm 4 showing that it did include the null hypothesis. 5 But I think it's still -- just because it's not 6 statistically significant, I think it's still 7 data, and I wouldn't completely discount it. 8 But it does -- does contain the null. The 9 numbers weren't super high, if I remember. But 10 on their -- I'll have to find it. 11 On -- in their abstract conclusion, they 12 still say that "The greatest ovarian cancer risk 13 associated with perineal talc use was observed in 14 the subgroup of women estimated to have made more 15 than 10,000 applications during years when they 16 were ovulating and had an intact genital tract 17 with the OR of 2.8 and a statistically 18 significant confidence interval of 1.4 to 5.4. 19 However, this exposure was found in only 20 14 percent of the women with ovarian cancer." 21 Q. Okay. But we were just asking -- you 22 mentioned the study as support for a 23 dose-response relationship in your report? 24 A. As evidence of a dose -- a 25 dose-response; again, with the caveat, which is</p>
<p style="text-align: right;">Page 263</p> <p>1 hypothesis. 2 Q. Do you see on Page 25, in the first 3 column on the left-hand side, the first full 4 paragraph, "In our analysis"? 5 Okay. The authors say, "In our analysis, we 6 first calculated all genital applications of talc 7 based on frequency and years of use. As a 8 continuous variable in a multivariate model, no 9 significant dose-response was observed between 10 total genital applications of talc and ovarian 11 cancer risk"; correct? 12 A. That's what it says. 13 Q. And the reason they excluded 14 hysterectomy and tubal ligation is the next 15 sentence, "because the translocation theory 16 assumes an open genital tract, we then excluded 17 application after tubal ligation or hysterectomy 18 but observed no appreciable change in the 19 dose-response." 20 In other words, still no significant 21 dose-response; correct? 22 A. That's what it says. 23 Q. So the authors interpreted both the 24 data you cite in your report as well as the data 25 you didn't cite in your report as showing no</p>	<p style="text-align: right;">Page 265</p> <p>1 here, that it includes the null hypothesis. 2 Q. Okay. And what about Cramer in 1999? 3 MR. ROTMAN: Objection. I don't think 4 that's a question. 5 MS. AHERN: Fair point. 6 BY MS. AHERN: 7 Q. In Cramer 1999, you've also cited as 8 evidence after dose-response, correct, on Page 35 9 of your report? 10 A. I see that. Yes. It's listed in a 11 reference list. 12 Q. And the authors, including Cramer, 13 basically say they "failed to demonstrate 14 consistent dose-response relationships with 15 measures of intensity of exposure." 16 MR. ROTMAN: Do you have -- do you have 17 the paper? 18 MS. AHERN: Do you want the paper? 19 MR. TISI: Is that the one you 20 identified before? 21 MS. AHERN: No. This is a new one. 22 MR. ROTMAN: She's getting the paper 23 out. 24 MS. AHERN: I thought I had it too. 25 Maybe it's in one of the boxes. Let me see if I</p>

<p style="text-align: right;">Page 266</p> <p>1 can find my own copy. 2 Okay. Sorry. This is the only copy I 3 have right now. 4 THE WITNESS: Okay. 5 MS. AHERN: We can mark it, if you 6 want. 7 BY MS. AHERN: 8 Q. It's a copy of the Cramer 1999 9 publication that you cited in your report in 10 support of dose-response. 11 MR. TISI: Are you marking it? 12 THE COURT: I can if you want me to. I 13 just didn't want to mark my copy. 14 MR. KLATT: I don't think I do. 15 MS. AHERN: That's all right. I don't. 16 We'll mark Cramer -- oops, no, we won't because 17 this is the wrong study. Sorry. The old "wrong 18 study" trick. 19 THE WITNESS: I can't find that 20 information. Oh, I've got the wrong reference. 21 Sorry. All righty. 22 (Article entitled "Genital Talc 23 Exposure and Risk of Ovarian Cancer" marked 24 Exhibit 21.) 25</p>	<p style="text-align: right;">Page 268</p> <p>1 in the table. Let me see. 2 Q. I think so. If you want to go to -- 3 A. Oh. 4 Q. You got it. 5 A. Yes. I see it now. Sorry. It was 6 buried in Table 3, very small print. Okay. Yes. 7 So Table 3, years of use. Yup. 8 Q. Do you see they're not showing a 9 statistically significant dose-response 10 relationship? 11 A. So for less than 20 years, the 12 confidence intervals were 1.16 to 3; at 20 and 30 13 and greater than 30, they did -- the confidence 14 intervals did include the null. 15 But, again, I don't know how many -- I can't 16 remember. Oh, here are the cases. 17 Yeah. So there are 55, less than 20 cases; 18 thirty-two 20 to 30; and 59 greater than 30. 19 Q. And you see also the frequency 20 analysis? It also did not find a significant 21 dose-response relationship as a statistically 22 significant dose-response relationship? 23 A. Yes. For less than 30 years, the 24 adjusted OR was 2.21 with a confidence interval 25 of 1.37 to 3.56.</p>
<p style="text-align: right;">Page 267</p> <p>1 BY MS. AHERN: 2 Q. Okay. So, Doctor, this is Exhibit 21, 3 which is "Genital Talc Exposure and Risk of 4 Ovarian Cancer," Dan Cramer, 1999. 5 A. Okay. 6 Q. This is something else. 7 Can you find -- I don't have it in front of 8 me, so I'm going to rely on you to find the 9 tables that show their dose-response analysis. 10 MR. ROTMAN: You made that Exhibit 21? 11 MS. AHERN: Yes. 12 MR. TISI: It's 21. Yes. 13 THE WITNESS: Would that be Table 2, 14 what you're referring to (indicating)? 15 BY MS. AHERN: 16 Q. I believe the numbers were -- they were 17 looked at in terms of zero years' duration, less 18 than 20, 20 to 30, and greater than 30. 19 Do you see that on there? 20 A. I'm looking. This one says "less 21 than -- frequency of use." 22 Q. There's a frequency and a duration. 23 A. Okay. 24 Q. Yeah. 25 A. Sorry. Why am I not seeing it? It's</p>	<p style="text-align: right;">Page 269</p> <p>1 The 30 to 39 was adjusted OR of 1.17 with 2 confidence intervals .78 to 1.76. 3 And the 40-plus adjusted OR was 1.57 with 4 confidence intervals of 0.8 to 3.10. 5 Q. So not only did the point estimate go 6 down with more use, but the higher the 7 concentration, there was also no statistical 8 significance; correct? 9 A. Yeah. I mean, the numbers -- so the 10 only one that doesn't include the null -- let me 11 just double-check. 12 Actually, there are two. So the less than 13 20 years or less than 30 per month are 14 statistically significant. 15 Q. It's only the first dose category in 16 each group -- 17 A. Yeah. 18 Q. -- shows statistical significance. 19 And as the doses got higher, the exposure 20 frequency got higher, the point estimates went 21 down and statistical significance went away; 22 correct? 23 A. The confidence intervals did include 24 the null. And I think this illustrates how 25 difficult sort of dose and frequency can be to</p>

<p style="text-align: right;">Page 270</p> <p>1 study because we don't really know what the doses 2 are, and we don't really have granularity as far 3 as frequency of use. Well, I have to look at -- 4 Q. These are studies that you cited in 5 your report as evidence of a dose-response, 6 correct, the Harlow and the Cramer papers? You 7 both cited yourself. 8 Did you evaluate the internal validity of 9 those studies and critically evaluate the methods 10 and study populations when you included them in 11 your report? 12 A. Let me -- well, I said -- this is the 13 sentence -- "Most have found an increased risk of 14 ovarian cancer with increased exposure." So, 15 yet, when studies have evaluated duration of 16 frequency of perineal talc use. 17 So this list is the studies that evaluated 18 duration and frequency of perineal talc use. And 19 I said, "Most have found an increased risk." So 20 what I'm citing here are the studies that looked 21 at duration and frequency. 22 Q. Okay. And we were referring to 23 Cramer's 2007 publication where he himself says 24 that the association has been challenged because 25 it's weak and because there's no clear increase</p>	<p style="text-align: right;">Page 272</p> <p>1 "application of talc." 2 "Another factor that may affect the 3 dose-response relationship is whether use 4 occurred at a time when the female tract was 5 open. There is evidence from several studies 6 that the talc/ovarian cancer association is 7 modified by closure of the female tract as a 8 result of tubal ligation or hysterectomy. 9 Q. Doctor, did they say they didn't find a 10 dose-response relationship? 11 A. I'm trying to find what they said other 12 than that on Page 355. 13 Yeah. They said, "Studies that have 14 dose-response, including this one, have failed to 15 demonstrate consistent dose-response 16 relationships." 17 But it goes on to qualify with the 18 difficulty of measuring dose and frequency, which 19 is what I described earlier. 20 Q. Mm-hmm. 21 (Article entitled "Perineal Talc 22 Exposure and Epithelial Ovarian Cancer Risk 23 in the Central Valley of California" marked 24 Exhibit 22.) 25</p>
<p style="text-align: right;">Page 271</p> <p>1 in risk with duration of use. 2 And you didn't agree with that statement, 3 and you referred me to Harlow 1992; correct? 4 A. I was going to where I mentioned the 5 dose-response studies. 6 Q. Okay. Just to button up and finish up 7 with Cramer 1999, if you look at Page 355, the 8 authors included, "They failed to demonstrate 9 consistent dose-response relationships with 10 measures of intensity of exposure." 11 Do you see that? 12 A. I'm sorry. Where are you? 13 Q. On Page 355. 14 A. Okay. I'm seeing "in attempting" -- 15 sorry. I see, "Most talc and ovarian cancer 16 studies that have addressed dose-response, 17 including this one, have failed to demonstrate 18 consistent dose-response relationships with 19 measures of the intensity of the exposure, 20 especially when the trend is examined among users 21 only. In attempting to address this weakness, we 22 point out that it is difficult to quantify the 23 amount of powder actually used and degree of 24 perineal dusting that might constitute an 25 application of talc," quote/unquote around</p>	<p style="text-align: right;">Page 273</p> <p>1 BY MS. AHERN: 2 Q. Okay. The next one -- are you done, 3 sorry, with that one? 4 A. If we're moving on, sure. 5 Q. If you're done. 6 The next one you mention, you cite in your 7 report for dose-response is Mills 2004, which I'm 8 handing you now marked as Exhibit 22. 9 Oh, yeah. We'll leave that here for right 10 now. 11 A. Okay. 12 MR. ROTMAN: Can I see the one you just 13 finished with? 14 MR. TISI: This is 22; right? 15 MS. AHERN: Yes, sir. 16 BY MS. AHERN: 17 Q. And this one, you're welcome to read 18 through it if you want. All I wanted to point 19 out is if you look right up front in the 20 abstract, a little more than midway down, they 21 say, "The odds ratio for ever use of talc was 22 1.37 with the confidence interval of 1.02 to 1.85 23 compared to never users. However, no 24 dose-response association was found." 25 Do you see that?</p>

<p style="text-align: right;">Page 274</p> <p>1 A. I see where it says that.</p> <p>2 Q. And if you want to look through there</p> <p>3 and convince yourself of that, go for it. I</p> <p>4 think the table that we're looking at is Table 2</p> <p>5 on Page 460.</p> <p>6 A. Yeah. The 4 to 12 years had an OR of</p> <p>7 1.86 that was statistically significant at 1.16</p> <p>8 to 2.98. But the others, which were never --</p> <p>9 which, of course, is the null, 4 to 12 years,</p> <p>10 which -- oh, the 13 to 30 was adjusted OR of</p> <p>11 1.45, confidence interval .9 to 2.32.</p> <p>12 And then the greater than 30 years was OR of</p> <p>13 1.22 with confidence interval of .72 and 2.08.</p> <p>14 So the 13 to 30 and the greater than 30 includes</p> <p>15 the null.</p> <p>16 And then if we look at frequency, cumulative</p> <p>17 use, frequency types duration, there was a</p> <p>18 statistically significant increase with second</p> <p>19 quartile and third quartile divisions. But then</p> <p>20 it dropped in the fourth quartile, the highest</p> <p>21 exposure.</p> <p>22 And, you know, again, sort of difficulty in</p> <p>23 measuring this. But you do see an increase in</p> <p>24 the second and third quartile, between the second</p> <p>25 and third, that was statistically significant.</p>	<p style="text-align: right;">Page 276</p> <p>1 Q. I was trying to point you a little bit</p> <p>2 toward this. It's Page 463. There's some</p> <p>3 discussion of it.</p> <p>4 If you look at the third paragraph down, "As</p> <p>5 in other studies, the present study did not find</p> <p>6 a clear dose-response based on duration of use or</p> <p>7 cumulative use."</p> <p>8 And then it says, "Limiting the analysis of</p> <p>9 dose-response to women who reported ever use of</p> <p>10 talc did not affect the results, data not shown.</p> <p>11 The lack of dose-response between talc use and</p> <p>12 epithelial ovarian cancer may be explained by the</p> <p>13 inability to quantify the actual amount of talc</p> <p>14 used per application and the timing of the</p> <p>15 application."</p> <p>16 A. Yeah. So with that caveat.</p> <p>17 Q. Well, the findings are what they are;</p> <p>18 right?</p> <p>19 The findings are no dose-response</p> <p>20 relationship?</p> <p>21 A. The findings are what they are. But,</p> <p>22 again, it's not an easy -- there's not huge</p> <p>23 numbers in these cases.</p> <p>24 And, again, you still don't know from woman</p> <p>25 to woman what one dose is, so there's a ton of</p>
<p style="text-align: right;">Page 275</p> <p>1 And then --</p> <p>2 Q. But the authors themselves interpret</p> <p>3 their data as no dose-response association;</p> <p>4 correct?</p> <p>5 A. In the abstract, that's what they</p> <p>6 state. I'm trying to figure out what their --</p> <p>7 what they said. They must have said a little bit</p> <p>8 more.</p> <p>9 Q. Doctor, you reviewed this study before;</p> <p>10 right?</p> <p>11 A. I did. Yes.</p> <p>12 Q. Okay.</p> <p>13 A. I'm just refreshing my memory.</p> <p>14 Q. Okay. If you look at Page 463.</p> <p>15 MR. ROTMAN: Are you changing the</p> <p>16 topic?</p> <p>17 MS. AHERN: No. Same topic.</p> <p>18 MR. ROTMAN: She was looking for</p> <p>19 something as part of a prior answer.</p> <p>20 BY MS. AHERN:</p> <p>21 Q. As part of your prior answer that there</p> <p>22 was no dose-response?</p> <p>23 A. As part of the answer that they stated</p> <p>24 that in the abstract. I was trying to find out</p> <p>25 where they had a discussion.</p>	<p style="text-align: right;">Page 277</p> <p>1 variability. It's not like a cigarette, where,</p> <p>2 you know, from one cigarette to the next or, you</p> <p>3 know, a drug dose is probably a more accurate</p> <p>4 analogy, you know.</p> <p>5 Q. True. But just because it's difficult</p> <p>6 to study, it doesn't mean if we could study it</p> <p>7 better, we would get a positive result, does it?</p> <p>8 A. I -- oh, my thing is not working. I</p> <p>9 think I have to plug my thing in.</p> <p>10 MR. ROTMAN: Can you?</p> <p>11 COURT REPORTER: I'd have to break to</p> <p>12 do it.</p> <p>13 MR. ROTMAN: Let's go off the record.</p> <p>14 THE VIDEOGRAPHER: Off the record.</p> <p>15 4:37 p.m.</p> <p>16 (A recess was taken.)</p> <p>17 THE VIDEOGRAPHER: Back on the record,</p> <p>18 4:44 p.m.</p> <p>19 BY MS. AHERN:</p> <p>20 Q. Okay. Doctor, you saw the Mills paper</p> <p>21 in front of you?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Could you look at your report on</p> <p>24 Page 21?</p> <p>25 (Witness complies.)</p>

<p style="text-align: right;">Page 278</p> <p>1 A. Okay.</p> <p>2 Q. Let's see, where is my copy?</p> <p>3 And turn to Page 3 of the Mills publication.</p> <p>4 A. Page 3, which would be Page 460?</p> <p>5 Q. That's a good question.</p> <p>6 Where is my Mills publication?</p> <p>7 MS. AHERN: Do you have it?</p> <p>8 MR. TISI: Sure.</p> <p>9 MS. AHERN: Thank you.</p> <p>10 Oh, I know where it is.</p> <p>11 BY MS. AHERN:</p> <p>12 Q. I'm sorry. I thought I had the</p> <p>13 specific passage marked. And I do, somewhere in</p> <p>14 here. Okay. Sorry. It's on Page 460. I</p> <p>15 apologize.</p> <p>16 A. Okay.</p> <p>17 Q. All right. Do you see on the Mills</p> <p>18 publication on Page 460 that bottom paragraph on</p> <p>19 the left, "ever use of talcum powder"?</p> <p>20 A. Yes.</p> <p>21 Q. And if you read down toward the bottom</p> <p>22 part of that paragraph, on the fourth line from</p> <p>23 the bottom, the sentence starts "Duration of</p> <p>24 use."</p> <p>25 A. Okay.</p>	<p style="text-align: right;">Page 280</p> <p>1 Q. Is there a reason that that entire</p> <p>2 portion of your report is copied identically from</p> <p>3 Mills except for the qualifier that the pattern</p> <p>4 was not clear-cut for dose-response?</p> <p>5 A. Well, I think it still has the same</p> <p>6 meaning.</p> <p>7 Q. Without the qualifier?</p> <p>8 A. I think the qualifier is in the -- in</p> <p>9 the data.</p> <p>10 Q. Okay.</p> <p>11 A. I don't think I was -- I wasn't trying</p> <p>12 to make it sound anything different than what it</p> <p>13 was. I think I was trying to report the data.</p> <p>14 Q. Okay. All right. And, Doctor, if you</p> <p>15 turn to Page 10 of your report, the section on</p> <p>16 inflammation.</p> <p>17 Are you there?</p> <p>18 A. Yes.</p> <p>19 Q. You start on the second paragraph under</p> <p>20 "Inflammation" discussing oxidative stress.</p> <p>21 A. Okay.</p> <p>22 Q. Okay. Were you aware that a</p> <p>23 significant amount of the section of your report</p> <p>24 on oxidative stress is copied verbatim? More</p> <p>25 than 60 percent of it, I think, is copied</p>
<p style="text-align: right;">Page 279</p> <p>1 Q. "Duration of use of talcum powder was</p> <p>2 associated with increased risk, although the</p> <p>3 pattern was also not clear-cut in that the point</p> <p>4 estimate peaked among those reporting 4 to 12</p> <p>5 years of use and declined somewhat among those</p> <p>6 reporting longer duration of use."</p> <p>7 Do you see that statement?</p> <p>8 A. I see that. Yup.</p> <p>9 Q. And if you look at your report on</p> <p>10 Page 21, the top paragraph, about midway, a</p> <p>11 little -- well, a third of the way down, you pick</p> <p>12 up with "Duration of use of talc was also</p> <p>13 associated with increased risk, although the risk</p> <p>14 peaked."</p> <p>15 Do you see that statement?</p> <p>16 A. Yes.</p> <p>17 Q. If you compare those statements, are</p> <p>18 they almost identical with the exception of the</p> <p>19 statement by Mills that the pattern was not</p> <p>20 clear-cut?</p> <p>21 A. They are similar. This might have</p> <p>22 been, like I described earlier, where, if I was</p> <p>23 taking notes, some of the language might have</p> <p>24 gotten incorporated, although I do have the</p> <p>25 citation.</p>	<p style="text-align: right;">Page 281</p> <p>1 verbatim from Dr. Saed's 2018 publication?</p> <p>2 A. Again, if the language is similar, it</p> <p>3 was not an intentional. I am citing him here, so</p> <p>4 it's -- you know, it's clear that those are the</p> <p>5 references. Again, it might have been due to</p> <p>6 note-taking, but the citation is clear.</p> <p>7 Q. Do you ever take verbatim language out</p> <p>8 of another scientist's work and not set it off in</p> <p>9 quotation marks in your professional work?</p> <p>10 A. I think I've cited the source here.</p> <p>11 It's -- so it's not -- again, it's not like I was</p> <p>12 intentionally copying his words. It was, again,</p> <p>13 probably an editing while I was taking notes, but</p> <p>14 the citations are clear.</p> <p>15 Q. Is your -- is the underlying</p> <p>16 understanding that you have related to oxidative</p> <p>17 stress and inflammation drawn primarily from</p> <p>18 Dr. Saed's work?</p> <p>19 A. No. I mean, oxidative stress and</p> <p>20 inflammation is something that we study -- that</p> <p>21 I've studied.</p> <p>22 Q. Have you ever published a study on</p> <p>23 oxidative stress or redox biology?</p> <p>24 A. I have not published on oxidative</p> <p>25 stress.</p>

<p style="text-align: right;">Page 282</p> <p>1 Q. What sort of work as a pathologist have 2 you done that incorporates redox biology? 3 A. Well, again, this is part of our 4 medical training. Certainly in training to be a 5 physician, that is something that we learn. And, 6 you know, pathologists do quite frequently come 7 across inflammatory -- inflammation literature. 8 Q. Are you -- is it your position that the 9 information in your report under "Inflammation" 10 that discusses oxidative stress and redox biology 11 is common knowledge among pathologists? 12 A. That oxidative stress and inflammation, 13 yes. I think -- yes. I think that's widely 14 accepted. 15 Q. The specific information contained on 16 Pages 10 and 11 of your report that was drawn 17 from Dr. Saed's work, is that information that is 18 common knowledge? 19 The specific enzymes that are discussed, the 20 research on these issues, is that specific 21 information there common knowledge? 22 A. It's common knowledge that these types 23 of cancer are associated with inflammation, and 24 certainly oxidative stress is part of 25 inflammation.</p>	<p style="text-align: right;">Page 284</p> <p>1 A. I did attribute -- I certainly cited 2 him in several places in this area. And, again, 3 it was not an intentional copying. Again, it 4 might have just happened with my editing, but I 5 certainly tried to cite everything that I was 6 looking at in the proper place. 7 But I do believe that it's common knowledge 8 that chronic inflammation can cause different 9 types of cancer. This is not really new data. 10 Q. Dr. Saed says that it's new data. 11 A. In what respect, though? If we're 12 talking about myeloperoxidase, yes. But I'm 13 talking about oxidative stress and chronic 14 inflammation with known association with certain 15 types of cancer. 16 Q. So it's your testimony that the 17 verbatim text that you used in the section from 18 Dr. Saed's 2018 paper was appropriately cited and 19 attributed to him? 20 MR. ROTMAN: Objection. 21 A. Again, I'm not sure it's absolutely 22 verbatim, but I certainly cited him in every 23 place that I was referencing. 24 Q. Okay. We'll just move on. 25 (Highlighted copy of Dr. Kane's</p>
<p style="text-align: right;">Page 283</p> <p>1 Q. Was this common knowledge to you before 2 you reviewed Dr. Saed's 2018 publication? 3 A. Yes. I was just citing his report at 4 this point. 5 Q. Are you aware you also cited his 6 underlying citations in the same spots that he 7 cited them? 8 A. That's possible because I reviewed his 9 citations as I was reading his citations. 10 Q. Did Dr. Saed give you permission to 11 copy his -- the language from his publication? 12 A. I wouldn't characterize it as 13 "copying." I think it may be similar language, 14 again, because I was writing as I was reading. 15 But I am certainly clearly citing his work and 16 the other citations. 17 Q. Do you agree that Dr. Saed's 2018 18 paper is a compilation of his own synthesis and 19 review of the underlying articles that he 20 incorporated into his paper, and do you think 21 it's appropriate for you to just lift the 22 language from his paper and the citations that he 23 found and synthesized and put it in your report 24 and not attribute it to him with quotation marks? 25 MR. ROTMAN: Objection.</p>	<p style="text-align: right;">Page 285</p> <p>1 expert report marked Exhibit 23.) 2 BY MS. AHERN: 3 Q. Doctor, I've marked as Exhibit 23 to 4 your deposition a highlighted copy of your report 5 that shows the verbatim text that has been 6 carried over from various publications into your 7 report. 8 If you turn to Page 10 and 11, you'll see 9 that the highlighted portions are copied directly 10 from Dr. Saed's work. 11 MR. ROTMAN: Do you have a copy for me 12 of this exhibit? 13 MS. AHERN: Oh. I do. Sorry about 14 that. 15 MR. ROTMAN: So we're at Page 10 and 16 11? 17 MS. AHERN: That's just for the Saed 18 publication. And there's one in there that Saed 19 was also on. 20 MR. ROTMAN: Does she have the Saed 21 publication in front of her? 22 MS. AHERN: I can find it for you. 23 BY MS. AHERN: 24 Q. But my point is, are you aware that 25 that -- that there's a significant portion of</p>

<p style="text-align: right;">Page 286</p> <p>1 that section of your report that is just 2 cut-and-pasted from Dr. Saed's work? 3 A. I don't believe -- again, it's -- it 4 wasn't intentional with the citations, and it 5 could have happened with my note-taking or other 6 suggested input. But, again, I cited -- I 7 certainly cited him in that section. 8 Q. Okay. 9 MR. TISI: Did you mark that? 10 MS. AHERN: Hmm? 11 MR. TISI: Did you mark that as an 12 exhibit? 13 MS. AHERN: Yes. I think it's 23. 14 Sorry. 15 MR. TISI: That's okay. 16 MR. ROTMAN: Do you have the Saed in 17 front of you? 18 BY MS. AHERN: 19 Q. I think it's -- it wasn't intentional 20 is your testimony, and it's probably just a 21 result of your note-taking process; is that 22 correct? 23 A. Well, because I cited him specifically, 24 certainly it wasn't intentional to be verbatim. 25 And I'm not sure exactly the process, but</p>	<p style="text-align: right;">Page 288</p> <p>1 biology and inflammation, are you? 2 A. I am not currently participating in a 3 study of oxidative stress or redox biology. 4 Q. You don't have any funding related to 5 oxidative stress and inflammation, do you? 6 A. No, I do not. 7 Q. Have you ever applied for any funding 8 in that area? 9 A. No. I have not. 10 Q. Have you ever authored a systematic 11 review of the literature on oxidative stress and 12 inflammation? 13 A. Oxidative stress and inflammation, no. 14 I don't believe I have. 15 Q. Have you ever authored a systematic 16 review of the literature on oxidative stress and 17 cancer? 18 A. No. I have not authored a systematic 19 review on that. 20 Q. Okay. Doctor, moving on to 21 inflammation and ovarian cancer. 22 Generally, on inflammation, can you cite to 23 a published experiment that was conducted in 24 animals in vivo that establishes a role of any 25 particular inflammatory cell or cytokine or</p>
<p style="text-align: right;">Page 287</p> <p>1 certainly I'm citing him several times there. 2 Q. Okay. That's fine. We'll just move 3 on. 4 And, Doctor, just to be clear, I understand 5 your testimony is that it is common knowledge to 6 pathologists that oxidative stress and 7 inflammation are related; correct? 8 A. Yes. 9 Q. Okay. But you are -- we're talking 10 about oxidative stress and redox biology 11 specifically as a field of study or research. 12 You're not an expert in that field of study 13 or research, are you? 14 A. I certainly have read literature in 15 that area. 16 Q. Does that make you an expert? 17 A. I'm -- I mean, I'm familiar with 18 literature in the area. That's -- that's my 19 answer. 20 Q. Okay. But you don't conduct studies in 21 oxidative stress and redox biology, do you? 22 A. I do not conduct studies in oxidative 23 stress and redox biology. 24 Q. You're not currently participating in a 25 study looking at oxidative stress or redox</p>	<p style="text-align: right;">Page 289</p> <p>1 enzyme in tumor regenesis? 2 A. Oh. Let me -- let me bring up my 3 inflammation section. Sorry. I'm just 4 refreshing myself as to what I stated in my 5 report. 6 Oh, this is low battery again. I don't 7 think this is plugged in. 8 MR. ROTMAN: Can we take five minutes 9 off the record? 10 MS. AHERN: Yes. 11 THE VIDEOGRAPHER: Off the record, 12 5:02 p.m. 13 (A recess was taken.) 14 THE VIDEOGRAPHER: Here begins Media 15 No. 6 in today's deposition of Sarah Kane, M.D. 16 Back on the record, 5:28 p.m. 17 (Article entitled "Talcum 18 powder, chronic pelvic inflammation and 19 NSAIDs in relation to risk of epithelial 20 ovarian cancer" marked Exhibit 24.) 21 BY MS. AHERN: 22 Q. Dr. Kane, I'm marking what's been -- 23 well, I'm marking Exhibit 24 to your deposition, 24 which is a copy of the Merritt 2008 publication. 25 And I'm sorry, I don't have an extra. I'm going</p>

<p style="text-align: right;">Page 290</p> <p>1 to share.</p> <p>2 It's "Talcum powder, chronic pelvic</p> <p>3 inflammatory -- sorry, chronic pelvic</p> <p>4 inflammation and NSAIDs in relation to risk of</p> <p>5 epithelial ovarian cancer."</p> <p>6 And you cite Dr. Merritt's paper a couple of</p> <p>7 times in your report; is that correct?</p> <p>8 A. I believe I cited it, yes.</p> <p>9 Q. I think you cite it as a statistically</p> <p>10 significant positive talc study on Page 17 of</p> <p>11 your report?</p> <p>12 A. Oh, let me get to that, if that's the</p> <p>13 section I'm thinking of.</p> <p>14 Q. There are a couple of places?</p> <p>15 A. There was -- yes. This happened in</p> <p>16 editing. I believe if this is -- so the sentence</p> <p>17 ended up, it originally didn't have the</p> <p>18 "statistically significant." It was just, you</p> <p>19 know, an odds ratio greater than one and listed.</p> <p>20 And then I mistakenly didn't delete. When I</p> <p>21 changed it to "statistically significant," for</p> <p>22 some reason -- I don't know if it happened in the</p> <p>23 editing between additions or something -- somehow</p> <p>24 I seem to remember deleting them. But in the</p> <p>25 final, they ended up all there. So that was a --</p>	<p style="text-align: right;">Page 292</p> <p>1 of multiple publications.</p> <p>2 A. Right.</p> <p>3 Q. You're saying that some of those</p> <p>4 publications shouldn't be in there because you</p> <p>5 added "statistically significant" as a criteria</p> <p>6 later?</p> <p>7 A. Exactly.</p> <p>8 Q. Okay. That's actually not my question</p> <p>9 about Merritt, but thank you.</p> <p>10 A. I knew that was going to come up --</p> <p>11 Q. That's okay.</p> <p>12 A. -- at some point.</p> <p>13 Q. While we're there, since we're sitting</p> <p>14 here looking at this, so these are -- you listed</p> <p>15 out case-control studies addressing talc, and</p> <p>16 they're supposed to be those that have</p> <p>17 statistically significant odds ratios; correct?</p> <p>18 A. That's correct. That was the</p> <p>19 intention.</p> <p>20 Q. And Gertig 2000 is there, and Houghton</p> <p>21 2014 are there, and they're obviously cohort</p> <p>22 studies?</p> <p>23 A. So, again, I think that somehow that</p> <p>24 paragraph got all -- and I didn't catch it in the</p> <p>25 final edits.</p>
<p style="text-align: right;">Page 291</p> <p>1 MR. ROTMAN: What page was this?</p> <p>2 A. -- typographical error.</p> <p>3 It's in there twice. I noticed it after I</p> <p>4 submitted it, and it was one of those --</p> <p>5 Q. Are you saying Merritt is not</p> <p>6 statistically significant?</p> <p>7 A. So I know which -- again, I'd have -- I</p> <p>8 have to go through. It's been a long day, and</p> <p>9 the names are starting to get all confused.</p> <p>10 Q. Yeah.</p> <p>11 A. But I know that that sentence, with</p> <p>12 "all of those" at the end of that sentence, is</p> <p>13 incorrect because I had changed -- I had meant to</p> <p>14 list cumulatively the statistically significant</p> <p>15 ones and ended up --</p> <p>16 Q. Okay. So just to clarify for the</p> <p>17 record, on Page 17, we're talking about the first</p> <p>18 full paragraph that says, "In addition to the</p> <p>19 Cramer 1982 study, numerous other case-control</p> <p>20 studies addressing talc use and ovarian cancer</p> <p>21 have shown statistically significant odds ratios</p> <p>22 greater than one indicating talc use is</p> <p>23 associated with an increased ovarian cancer</p> <p>24 risk."</p> <p>25 And then there's a string cite with a number</p>	<p style="text-align: right;">Page 293</p> <p>1 Q. Okay.</p> <p>2 A. I know that that was at least a</p> <p>3 different paragraph at first, possibly two</p> <p>4 paragraphs that got condensed. And then somehow,</p> <p>5 the references didn't get changed in the final.</p> <p>6 Q. Okay. Do you happen to know -- and if</p> <p>7 you don't it's okay -- but do you happen to know</p> <p>8 which of these studies should be there and which</p> <p>9 should be removed?</p> <p>10 A. Off -- I would want to look just to</p> <p>11 make sure.</p> <p>12 Q. Okay.</p> <p>13 A. But I'm -- if I am -- I'd want to look</p> <p>14 just to make sure, but I know there are some that</p> <p>15 should not be there.</p> <p>16 Q. All right. But looking at Merritt,</p> <p>17 there are a couple of places where Merritt is</p> <p>18 cited in your report. One is Page 17 in that</p> <p>19 paragraph we just looked at. Another is Page 28</p> <p>20 in Section -- the "Pooled study regarding talc</p> <p>21 use and ovarian cancer" section.</p> <p>22 It says some -- let's see, you're talking</p> <p>23 about the advantages of pooled studies, and you</p> <p>24 cited Merritt 2008.</p> <p>25 A. Okay.</p>

<p style="text-align: right;">Page 294</p> <p>1 Q. And then on Page 35, Merritt is cited. 2 "Studies evaluating duration and frequency of 3 perineal use, most have found an increased risk 4 of ovarian cancer with increased exposure." 5 We already went through this paragraph 6 earlier -- 7 A. Yeah. Yeah. 8 Q. -- and discussed Merritt a little bit 9 in that context. 10 MR. ROTMAN: Page 30 -- the last one 11 was Page 35? 12 MS. AHERN: Thirty-five. Yeah. I 13 apologize. We may not have discussed Merritt. 14 BY MS. AHERN: 15 Q. But looking at Merritt now, you're 16 aware that Merritt looked specifically at 17 inflammatory conditions as part of their 18 exploration of the hypothesis that chronic 19 inflammation could lead to ovarian cancer; is 20 that right? 21 A. Yes. There was a component from what I 22 remember. 23 Q. They say in the abstract that "Chronic 24 inflammation has been proposed as the possible 25 causal mechanism that explains the observed</p>	<p style="text-align: right;">Page 296</p> <p>1 endometriosis. 2 And do you see if you turn to -- I'm trying 3 to get through this quickly. You're welcome to 4 point out anything you want, but I kind of want 5 to move us along. 6 A. Okay. 7 Q. If you look at the "Discussion" 8 section, I, unless I missed it, on Page 174, the 9 right-hand column, second full paragraph, they 10 note that "It has been hypothesized that talc is 11 linked to ovarian cancer development through 12 inflammation. However, evidence linking an 13 inflammatory response with talc contamination of 14 the ovaries is lacking." 15 Do you agree or disagree with that statement 16 that evidence linking an inflammatory response 17 with talc contamination of the ovaries is 18 lacking? 19 A. I don't know if I would phrase it that 20 way. Have there been studies that have followed 21 talc from application up to the ovaries and 22 documenting an inflammatory response after talc? 23 No. There's not going to be that study. 24 That would be -- I don't think you could do 25 that study today with talc being called by the</p>
<p style="text-align: right;">Page 295</p> <p>1 association between certain risk factors such as 2 the use of talcum powder or talc in the pelvic 3 region and epithelial ovarian cancer." 4 Do you see that? It's in the abstract, the 5 first sentence? 6 A. Yeah. Okay. The first sentence. 7 Q. Okay. They go on to say, "To address 8 the issue, we evaluated the potential role of 9 chronic local ovarian inflammation in the 10 development of the major subtypes of epithelial 11 ovarian cancer." 12 Do you see that? 13 A. Yes. 14 Q. Okay. And just want to ask you: They 15 conducted the study as a case-control study 16 looking at 2319 women with epithelial ovarian 17 cancer; correct? 18 A. I don't remember the exact number, but 19 I will -- I will -- 20 Q. I think that's -- that's okay. 21 A. I don't remember the exact number. 22 Q. Okay. So they looked at a number of 23 factors that are theoretically associated with 24 chronic inflammation, didn't they, including 25 pelvic inflammatory disease and talc use,</p>	<p style="text-align: right;">Page 297</p> <p>1 IARC a possible carcinogen. I don't think you 2 could design that study right now and do that in 3 women. 4 But, again, I think -- I think it's still a 5 highly compelling, plausible mechanism because we 6 know talc can cause inflammation, and 7 inflammation is associated with certain cancers, 8 including certain types of ovarian cancers. 9 So I don't know if I would state it that 10 way. 11 Q. When you say inflammation is associated 12 with ovarian cancer, what studies are you 13 referring to? 14 A. I'm referring to, for example, clear 15 cell carcinomas that have arisen from 16 endometriotic lesions that we've talked about 17 before. 18 Q. And those cells are -- the originating 19 cells are thought to come from the endometrium 20 itself, the uterus; correct? 21 A. I don't know if we know for sure. I 22 mean, is it endometriosis that's in the ovary 23 causing chronic inflammation in the ovarian cells 24 that are causing the clear cell? I don't know if 25 that's been completely delineated.</p>

<p style="text-align: right;">Page 298</p> <p>1 Q. But there are markers that will 2 distinguish ovarian surface epithelial cells from 3 endometrioid cells which resemble endometrial 4 cells; correct?</p> <p>5 A. There are some stains that you can do. 6 But, again, I don't know if it's going to be -- 7 been completely elucidated.</p> <p>8 Q. Are you aware of recent studies that 9 have demonstrated that there is some abnormality 10 in the endometrium of women who develop 11 endometriosis when compared to women who don't 12 develop endometriosis?</p> <p>13 A. I'm aware that retrograde migration of 14 the endometrium is thought to -- has been 15 associated with endometriosis. I don't know what 16 you mean by "abnormalities" of the -- you have to 17 be more specific. I can't --</p> <p>18 Q. I don't have the publication with me. 19 I was just asking if you were aware of those 20 studies.</p> <p>21 A. I probably read them at some point, but 22 off the top of my head, I'm not really sure 23 without knowing more specifically.</p> <p>24 Q. And would you agree that the studies, 25 though, that show a decreased risk of ovarian</p>	<p style="text-align: right;">Page 300</p> <p>1 inflammatory mechanism in the development of 2 epithelial ovarian cancer. However, experimental 3 evidence that perineal talc use elicits an 4 inflammatory response in the ovaries is lacking, 5 and overall, we conclude that chronic 6 inflammation does not play a major role in 7 development of ovarian cancer."</p> <p>8 Is there a reason you didn't cite the 9 Merritt study in your report specifically when 10 discussing evidence of chronic inflammation and 11 ovarian cancer, a link between those two?</p> <p>12 A. In the places that I -- let me just 13 double-check. Places that I mention, was I 14 not -- I wasn't talking about inflammation. Is 15 that what you're --</p> <p>16 Q. Yes. You agree you cited Merritt in 17 several places in your report?</p> <p>18 A. Yes.</p> <p>19 Q. But you didn't cite anything about the 20 inflammation findings from Merritt.</p> <p>21 A. I'm not sure I can completely agree 22 with their conclusion. It's true we don't 23 have -- like I mentioned before, we don't have a 24 study that has looked at women who use talc, 25 follow it up, and then see chronic inflammation</p>
<p style="text-align: right;">Page 299</p> <p>1 cancer for women who have tubal ligation are 2 studies -- well, are more highly associated with 3 endometrioid clear cell carcinomas than with 4 high-grade serous?</p> <p>5 A. With tubal ligation, off the top of my 6 head, I believe that's -- that that's the case. 7 But with salpingectomy, which removes the 8 fallopian tube fimbriae, there's -- that 9 decreases the risk of serous carcinomas.</p> <p>10 Q. To a lesser extent, then, the decrease 11 for clear cell and endometrioid, which some 12 people have suggested supports the retrograde 13 migration of endometrial cells into the abdominal 14 cavity?</p> <p>15 A. Some people have said that that 16 supports the retrograde migration of the 17 endometrial cells. That is correct.</p> <p>18 Q. And I got off topic. We're looking at 19 Merritt. Page 174, if you look, let's see -- 20 here it is. Sorry. I apologize, on Page 175. 21 The very bottom of the summary paragraph, it 22 says, "The elevation in ovarian cancer risk 23 associated with use of talc in the perineal 24 region that we and others have observed has been 25 regarded as the main evidence supporting an</p>	<p style="text-align: right;">Page 301</p> <p>1 in the ovary.</p> <p>2 But I think that's going to be -- again, we 3 don't know how long that chronic inflammation is 4 going to be there. We don't know what dose is 5 getting into the ovary.</p> <p>6 I still think -- and, again, this is the 7 plausibility part of it -- I think there's still 8 compelling evidence that talc can cause an 9 inflammatory response that would explain the risk 10 of increased risk of ovarian cancer with talcum 11 powder products.</p> <p>12 So, I mean, I certainly read this. It had 13 some good information in it. I don't think I was 14 purposely trying to leave out something that had 15 evidence. This was their opinion.</p> <p>16 And I'm -- I don't know if I would phrase it 17 that way, the exact words that they use.</p> <p>18 Q. Well, if those are exactly their 19 findings here -- if you look at the top of the 20 summary paragraph, "In summary, most factors that 21 could potentially cause ovarian inflammation such 22 as pelvic inflammatory disease, HPV infection, 23 and postpubertal mumps were not associated with a 24 significant elevation in ovarian cancer risk in 25 our study. In addition, the expected corollary,</p>

<p style="text-align: right;">Page 302</p> <p>1 an inverse association with regular use of 2 anti-inflammatory medications, was also not 3 observed -- or was not observed." 4 A. Yes. Yeah. Yeah. 5 Q. They looked at multiple sources or 6 multiple causes of inflammation in the pelvic 7 region and did not find an association with the 8 risk of ovarian cancer, and they didn't find a 9 decreased risk in people that used 10 inflammatory -- anti-inflammatory medications. 11 A. I think I mentioned -- 12 Q. So this is an inflammation study, isn't 13 it? 14 A. Yeah. I think I mentioned in -- about 15 NSAIDs that I might have cited them in that 16 section, that the evidence was not consistent 17 with NSAIDs, if I remember correctly. 18 I definitely looked at this paper when I was 19 looking at NSAID and aspirin use and certainly 20 inflammation as well. So... 21 Q. It's actually not cited anywhere with 22 NSAID use or regarding inflammation at all. 23 So maybe it was an earlier draft and was 24 removed at some point? 25 A. It's possible.</p>	<p style="text-align: right;">Page 304</p> <p>1 Q. I'm sorry. I'm just referring 2 generally. 3 Do your opinions, in part, depend on the 4 finding of talc in ovaries? 5 A. No. Because I think, again, it's 6 difficult to find talc in the ovaries. So I 7 would not expect to see -- to find, to 8 histologically find talc in every ovary of a 9 woman who has used talcum powder products. I 10 think that would be extremely difficult to do in 11 every patient. 12 And I know we talked about the MUC-1 theory 13 earlier, but if that is the mechanism, that would 14 not require talc to get to the ovary. 15 So, no, I don't think it's necessary to find 16 talc in the ovary in every woman to come -- 17 that's a user. 18 Q. Let's talk about evidence for 19 talc-induced inflammation in the ovary. 20 For instance, you've cited the Heller study 21 from 1996 in your "Migration translocation, 22 inhalation, and lymphatic transport" section on 23 Page 14. 24 A. Mm-hmm. 25 Q. Heller actually states in their study</p>
<p style="text-align: right;">Page 303</p> <p>1 Q. And you also -- you cite -- you do cite 2 some of the NSAID studies and aspirin studies, 3 but you leave out others. You leave out Baandrup 4 2013, which was a negative study; Bonovas, 2005, 5 which was a negative study; Ni, 2012, which was a 6 negative study. 7 When you did your review of inflammation 8 including anti-inflammatory medications and the 9 risk of ovarian cancer, did you pull out more 10 studies in review than you actually included in 11 your report? 12 A. Yes. There are definitely more studies 13 than were cited in my report. 14 Q. Is there a reason you didn't cite the 15 negative studies? 16 A. I didn't intentionally leave out the 17 negative studies, but I do mention that the 18 evidence had been inconsistent with NSAID. 19 Q. Okay. And you mentioned the Heller 20 study in a couple of places. You mentioned 21 several times that part of your plausibility 22 opinions involve the fact that talc has been 23 observed in the ovaries; correct? 24 A. Can you show me? I'm sorry. I just 25 want to make sure.</p>	<p style="text-align: right;">Page 305</p> <p>1 that they did not find on their H&E slides any 2 response -- any expected response to talc 3 particles. 4 Do you remember that? 5 A. I do remember that vaguely. Yes. 6 Q. Did any of the studies that you cite in 7 that section for the proposition that talc has 8 been found in ovarian tissue, did any of those 9 find a reaction to talc in the ovaries? 10 A. I don't believe the studies that have 11 found talc in the ovaries have all looked for 12 chronic inflammation. Some of them, if I'm 13 remembering correctly, I don't know if they all 14 looked histologically; but the ones that did, I 15 don't believe they had mentioned finding chronic 16 inflammation near the talc particles. 17 But again, you know, depending on how long 18 that inflammatory response is going to be there, 19 depending how long that particular talc particle 20 has been there, you wouldn't necessarily expect 21 to still see it 20 years later. 22 Q. Okay. In the Heller study, they looked 23 at ovarian tissue -- ovaries from one of their 24 subjects who had 1.7 or approximately 25 1.669 million particles per gram of wet weight by</p>

<p style="text-align: right;">Page 306</p> <p>1 electron microscopy and found on hematoxylin and 2 eosin stain slides from the analyzed sections of 3 the tissue that no evidence of response to talc 4 such as foreign body giant cell reactions or 5 fibrosis in the tissue. 6 Is that consistent with the other studies 7 that have reported findings from H&E have also 8 reported no response to talc or supposed talc 9 they found? 10 What is an alternative explanation for how 11 microscopists doing these sorts of studies might 12 find talc by TEM or SEM without any histologic 13 response -- 14 MR. ROTMAN: Objection. 15 Q. -- to talc in the tissue? 16 A. Well, I think I addressed that a little 17 earlier. Again, I don't know -- we don't know 18 how long a chronic inflammatory response would be 19 there after a particular talc particle lands on 20 the ovary. 21 But the important thing would be that that 22 chronic inflammation, the initial chronic 23 inflammation, whenever that may be, however long 24 it is there, causes oxidative stress that induces 25 an oncogenic change in an ovarian cell or</p>	<p style="text-align: right;">Page 308</p> <p>1 MS. AHERN: What number are we on? 2 COURT REPORTER: Twenty-five. 3 MS. AHERN: Twenty-five. 4 MR. TISI: So 24 was -- 5 MS. AHERN: We'll wait. 6 (Article entitled "The 7 relationship between perineal cosmetic talc 8 usage and ovarian talc particle burden" 9 marked Exhibit 25.) 10 A. I believe they went through standard 11 electron microscopy methods, which controls for 12 contamination. 13 BY MS. AHERN: 14 Q. How? 15 A. I don't know if it goes through the 16 whole -- but they're very careful in how they 17 handle tissue before they prep for electron 18 microscopy. 19 Q. Doctor, do you know where they got the 20 tissue from? 21 A. Yeah. It's listed. 22 Q. Did they collect the tissue themselves 23 from the patient in a particulate-free 24 environment and handle it with particulate-free 25 gloves in containers, or did they get it from</p>
<p style="text-align: right;">Page 307</p> <p>1 fallopian tube cell, for that matter. 2 So -- and these are very small studies that 3 looked at histologic -- that looked 4 histologically for talc in these ovaries. 5 So, you know, I don't necessarily think -- I 6 don't think that you would have to find chronic 7 inflammation if you're looking at an ovary at a 8 particular point in time when we're talking about 9 long-term talc use from, you know, up to 20 years 10 ago or something. 11 Q. Well, if they're finding 1.7 million 12 particles per gram of wet tissue right then and 13 there, and their slides from that time period 14 don't show any response whatsoever to talc that 15 they would expect to see, what's an alternative 16 explanation? 17 A. An alternative explanation is that 18 there was chronic inflammation, and it has since 19 resolved. 20 Q. How about there might be contamination 21 of their samples with talc, which is ubiquitous 22 in many laboratories? 23 A. I believe they -- I have to look at the 24 study to -- do you have the study? 25 MR. ROTMAN: Thank you. What number?</p>	<p style="text-align: right;">Page 309</p> <p>1 hospital paraffin-embedded tissue? 2 If you look on Page 1508, "Ovarian tissue in 3 blocks was reparafricanized, rehydrated, blotted dry 4 and weighed, and then digested with reagents." 5 A. So I think these women were talc users. 6 I'm trying to find controls that they had ovaries 7 from -- if I remember correctly, they had ovaries 8 from fetal cases that did not show talc, if I 9 remember correctly. I'm trying to find that. 10 Yeah. "In addition, the ovaries of two 11 stillborn fetuses were analyzed as negative 12 controls." 13 Q. Does it say anything about where those 14 stillborn fetus ovaries came from and if they 15 were handled in the same hospital in the same way 16 that the paraffinized blocks were handled? 17 A. If they didn't have a separate section 18 of their methods how they handled it, it would be 19 the same methodology. 20 Q. Well, assuming it's not contamination 21 and there's still no reaction to talc, another 22 alternative explanation might be that talc 23 doesn't cause chronic inflammation in the 24 ovaries. 25 A. But they didn't find talc in their</p>

<p style="text-align: right;">Page 310</p> <p>1 negative controls, which were fetal females that 2 would never have been exposed to talc. 3 Q. Except for after the tissues were taken 4 from the fetuses and processed? 5 A. I'm just trying to find where they -- 6 what they did. 7 Q. What I wonder and what I don't think is 8 in the paper, unless you can find it, is an 9 explanation for how the fetal ovaries were 10 obtained and processed. 11 Did they come from the same hospital 12 system -- 13 A. It would be the same. 14 Q. -- from the laboratory so that any 15 contamination that occurred to those tissues 16 prior to the Heller group getting them was 17 accounted for? 18 Or did they purchase them separately through 19 a company or something else that handled them 20 differently from the hospital samples? 21 MR. ROTMAN: Objection. 22 A. If those were obtained differently, it 23 should have been in the methodology. So the fact 24 that it's not there, the next sentence after they 25 say, "In addition, the ovaries of two stillborn</p>	<p style="text-align: right;">Page 312</p> <p>1 something that would happen over days. Chronic 2 inflammation is generally longer, but it still 3 resolves. 4 Q. And are -- for instance, pelvic 5 inflammatory disease is -- the effects of pelvic 6 inflammatory disease can be seen by pathologists 7 for a very long time; correct? 8 A. You can see fibrosis. So... 9 Q. And one of the things that you 10 mentioned earlier is that talc can cause 11 fibrosis? 12 A. Talc can cause fibrosis. You get -- in 13 the ovary, however, you will get surface 14 fibrosis, generally, from the mesothelial cells 15 in the surface. 16 But, again, you're not always going to have 17 fibrosis with chronic inflammation, either. 18 Q. If it's chronic inflammation that is 19 significant enough to lead to a transformative 20 event, shouldn't you expect to see some evidence 21 of that chronic inflammation? 22 A. Well, we don't know how much chronic 23 inflammation is necessary to cause a carcinogenic 24 effect. 25 Q. By analogy, wouldn't you look at</p>
<p style="text-align: right;">Page 311</p> <p>1 fetuses were analyzed as negative controls," that 2 is where, if it had been a different methodology 3 or different purchased ovarian cell blocks from 4 fetuses, which I have never -- anyway, it would 5 be -- it would be there. And it's not. 6 Q. Hmm. So my next question is: I had 7 asked you earlier if there was an alternative 8 explanation for why there's no tissue response 9 seen in this study to talc particles, and you 10 said it could be because the chronic inflammation 11 was there and not there at the time that they 12 looked at the H&Es? 13 A. Yeah. I mean, you're looking at an 14 ovary at a very -- at one time point. So we 15 don't know how long those talc particles were 16 there. We don't know if -- how long -- we don't 17 know how long the chronic inflammation is there. 18 But the important thing is that the chronic 19 inflammation would cause an event to change to an 20 oncogenic phenotype, gene type. 21 Q. So chronic inflammation is, by 22 definition, chronic; correct? Doesn't just -- it 23 doesn't just resolve in a couple of days. 24 It's ongoing; is that correct? 25 A. It is -- acute inflammation would be</p>	<p style="text-align: right;">Page 313</p> <p>1 something like ulcerative colitis and colon 2 cancer since that seems to be a fairly 3 well-established association? 4 A. Yes. And as soon as patients are 5 diagnosed with ulcerative colitis and Crohn's 6 disease, they are carefully followed at the 7 beginning. We don't wait 20 years to start 8 following them. We know that, you know, the risk 9 is there. As soon as they're diagnosed, we know 10 there is a risk for increased cancer, so we start 11 surveying them. 12 Q. But there's massive evidence of 13 inflammation -- tissue-damaging inflammation in 14 ulcerative colitis; correct? 15 A. Not always massive, but there's chronic 16 inflammation. 17 Q. Throughout the entire GI tract or 18 bowel? 19 A. In -- it's not always the whole, but 20 yeah, there's chronic inflammation in the 21 intestines. 22 Q. There's nothing in the literature that 23 suggests that talc causes that kind of an 24 inflammatory reaction, is there? 25 A. That talc causes a chronic</p>

<p style="text-align: right;">Page 314</p> <p>1 inflammation?</p> <p>2 Q. That talc causes that sort of chronic</p> <p>3 inflammatory reaction.</p> <p>4 A. Well, I showed you some excerpts where</p> <p>5 they mention lymphocytic and plasmacytic</p> <p>6 inflammation due to talc. We know that talc</p> <p>7 causes an acute inflammation. I know we weren't</p> <p>8 talking about acute inflammation, but we know it</p> <p>9 causes acute inflammation in the -- after a</p> <p>10 pleurodesis. And I'm sure you could have</p> <p>11 lymphocytes in plasma cells there too.</p> <p>12 Again, I don't think it's the -- sure. The</p> <p>13 amount and duration of chronic inflammation, I</p> <p>14 mean, would that increase the risk? But even a</p> <p>15 small amount of chronic inflammation for a</p> <p>16 relatively short period of time, I think it's</p> <p>17 plausible.</p> <p>18 And, again, this is all under the plausible</p> <p>19 thing that this would cause a mutagenic effect.</p> <p>20 Q. Can you name other chronic inflammatory</p> <p>21 conditions that are not associated with cancer?</p> <p>22 A. Chronic inflammatory conditions that</p> <p>23 are not associated with cancer? Well, I'm not</p> <p>24 sure we absolutely know every -- that a chronic</p> <p>25 inflammatory condition won't cause a cancer,</p>	<p style="text-align: right;">Page 316</p> <p>1 Q. Have you ever diagnosed a patient with</p> <p>2 a talc-related ovarian cancer?</p> <p>3 A. It's entirely possible that I have, but</p> <p>4 I have not used polarized light microscopy on</p> <p>5 ovarian tumors, so it's possible I have and</p> <p>6 didn't look for talc -- didn't look for talc.</p> <p>7 MR. KLATT: Objection. Nonresponsive.</p> <p>8 Q. My question was: Have you ever</p> <p>9 diagnosed a patient with a talc-related ovarian</p> <p>10 cancer, meaning you have said, "Your cancer is</p> <p>11 related to talc use"?</p> <p>12 A. Well, first of all, I wouldn't have</p> <p>13 said that if I'm not looking for talc.</p> <p>14 But secondly, in our pathology reports, even</p> <p>15 though we're thinking and looking at causation,</p> <p>16 we're not necessarily putting in our individual</p> <p>17 patient reports what caused their cancer.</p> <p>18 We're certainly putting the diagnosis</p> <p>19 together with their medical history and their --</p> <p>20 to kind of make all the pieces fit together, but</p> <p>21 we're not necessarily in every patient putting</p> <p>22 out a report on what causes their cancer.</p> <p>23 MR. KLATT: Objection. Nonresponsive.</p> <p>24 MS. AHERN: Objection. Nonresponsive.</p> <p>25 Q. I just want to know if you've ever</p>
<p style="text-align: right;">Page 315</p> <p>1 but -- so I'm not really sure. I'm not really</p> <p>2 sure what you're getting at.</p> <p>3 Q. Can you list five chronic inflammatory</p> <p>4 conditions?</p> <p>5 A. That don't cause --</p> <p>6 Q. Just list five chronic inflammatory</p> <p>7 conditions.</p> <p>8 A. Well, we have rheumatoid arthritis that</p> <p>9 increases risk of lymphomas. We have</p> <p>10 Helicobacter pylori infections that increase</p> <p>11 gastric cancer. We have the ulcerative colitis,</p> <p>12 Crohn's disease, that increase the risk of</p> <p>13 cancer. Agent exposures like asbestos that</p> <p>14 causes chronic inflammation and causes cancer.</p> <p>15 HPV infection causes cancer. I mean...</p> <p>16 Q. Can you name one that doesn't involve a</p> <p>17 virus or an underlying immune dysfunction?</p> <p>18 A. I named asbestos.</p> <p>19 Q. Asbestos.</p> <p>20 And was there another?</p> <p>21 A. Again, I don't know if we have all the</p> <p>22 data on potential carcinogens and whether or not</p> <p>23 they cause chronic inflammation for sure. I</p> <p>24 think that, you know, we're still getting that</p> <p>25 data.</p>	<p style="text-align: right;">Page 317</p> <p>1 actually diagnosed a patient with a talc-related</p> <p>2 ovarian cancer. It sounds like the answer is no.</p> <p>3 If it is, it's okay. I need an answer.</p> <p>4 A. I'm trying to answer your question.</p> <p>5 Honestly, it's entirely possible that I have.</p> <p>6 But have I specifically put in a patient's</p> <p>7 report, "This ovarian cancer was caused by talc,"</p> <p>8 no.</p> <p>9 Q. Thank you. That's all I was asking.</p> <p>10 What about at tumor boards? Do you attend</p> <p>11 tumor boards?</p> <p>12 A. I do.</p> <p>13 Q. Have you ever suggested in a tumor</p> <p>14 board meeting with other colleagues that a</p> <p>15 particular patient's ovarian cancer was caused by</p> <p>16 talc use?</p> <p>17 A. I've certainly discussed with</p> <p>18 oncologists and radiation oncologists about my</p> <p>19 recent work. Again, it's been only in the last</p> <p>20 year and a half that I have really done this deep</p> <p>21 dive in this literature.</p> <p>22 And I've certainly talked to radiation</p> <p>23 oncologists, oncologists about it at tumor boards</p> <p>24 in a way of sort of educating them about my</p> <p>25 findings, but we haven't discussed in the context</p>

<p style="text-align: right;">Page 318</p> <p>1 of a particular patient.</p> <p>2 Q. And were these discussions with</p> <p>3 radiation oncologists, were these people that</p> <p>4 focused on -- if they focus on -- gynecologic</p> <p>5 malignancies? Were they more pulmonary? Is</p> <p>6 there a difference with radiologists in terms of</p> <p>7 specialty?</p> <p>8 A. There are some subspecialties. In this</p> <p>9 one, they were more general radiation</p> <p>10 oncologists.</p> <p>11 Q. Okay.</p> <p>12 MS. AHERN: How much time do we have?</p> <p>13 THE VIDEOGRAPHER: Fifteen minutes.</p> <p>14 MS. AHERN: I'm going to turn it over</p> <p>15 to my colleagues so they have an opportunity to</p> <p>16 ask questions. Thank you very much. I</p> <p>17 appreciate it.</p> <p>18 THE WITNESS: Thank you.</p> <p>19 MR. KLATT: How much time do we have?</p> <p>20 We're at 6:37 right now.</p> <p>21 Are you ready for me to continue?</p> <p>22 CROSS-EXAMINATION</p> <p>23 BY MR. KLATT:</p> <p>24 Q. Dr. Kane, are you ready to continue?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 320</p> <p>1 asbestos in it.</p> <p>2 Are you choosing to believe the plaintiffs'</p> <p>3 asbestos experts over Ms. Pier's testimony?</p> <p>4 MR. TISI: Objection.</p> <p>5 A. Again, I think these were pieces of</p> <p>6 information for me. I wasn't relying on her --</p> <p>7 the exhibit from her testimony for my general</p> <p>8 causation. I wasn't -- and I didn't see</p> <p>9 Dr. Longo's reports until very late in my process</p> <p>10 from what I recall.</p> <p>11 It's interesting information for me. It's</p> <p>12 informative in that if the talcum powder products</p> <p>13 cause [sic] asbestos, that certainly lends</p> <p>14 significance to plausibility. But I'm --</p> <p>15 MR. ROTMAN: Do you want to reread your</p> <p>16 answer there? I think you misspoke.</p> <p>17 THE WITNESS: Okay. Sorry.</p> <p>18 A. Yes. I did. If the talcum powder</p> <p>19 contains asbestos, that certainly adds to the</p> <p>20 plausibility. But I'm not opining on whether or</p> <p>21 not talcum powder products contain asbestos.</p> <p>22 Q. And you wouldn't have the expertise to</p> <p>23 decide that Dr. Longo's testimony about asbestos</p> <p>24 in talc is more credible than Ms. Pier's</p> <p>25 testimony about asbestos in talc, do you?</p>
<p style="text-align: right;">Page 319</p> <p>1 Q. Can you hear me okay?</p> <p>2 A. Yes.</p> <p>3 Q. Yes. Dr. Kane, my name is Mike Klatt,</p> <p>4 and I represent a company called Imerys Talc</p> <p>5 America in this case.</p> <p>6 Before this lawsuit, have you ever heard of</p> <p>7 Imerys Talc America?</p> <p>8 A. I don't believe I had, no.</p> <p>9 Q. Do you know what Imerys Talc America</p> <p>10 does?</p> <p>11 A. From my understanding, they mine talc,</p> <p>12 and they supply -- they're the talc -- one of the</p> <p>13 talc suppliers for Johnson & Johnson.</p> <p>14 Q. You said earlier you reviewed an</p> <p>15 exhibit of Julie Pier's deposition.</p> <p>16 Do you know who Julie Pier is?</p> <p>17 A. I know she was a designated</p> <p>18 representative. I don't know if it was for J&J</p> <p>19 or for Imerys off the top of my head.</p> <p>20 Q. Ms. Pier works at Imerys, and she's an</p> <p>21 expert microscopist and at analyzing talc for any</p> <p>22 extraneous substances like asbestos.</p> <p>23 She testified that the evidence you looked</p> <p>24 at did not indicate in any way that talc that</p> <p>25 ended up in Johnson & Johnson's baby powder had</p>	<p style="text-align: right;">Page 321</p> <p>1 A. I have a, I would say, cursory</p> <p>2 knowledge of how they would test for asbestos. I</p> <p>3 couldn't say that I am an expert in the methods</p> <p>4 that they use to detect asbestos.</p> <p>5 Q. But my specific question is: You don't</p> <p>6 have the expertise to determine that Dr. Longo's</p> <p>7 testimony about asbestos and talc is more</p> <p>8 credible with or more believable or more</p> <p>9 scientifically valid or less scientifically valid</p> <p>10 than Ms. Pier's testimony about asbestos and</p> <p>11 talc; correct?</p> <p>12 That's my question.</p> <p>13 A. Again, it's pieces of information for</p> <p>14 me. I don't know anything, really, about</p> <p>15 Dr. Longo versus Ms. Pier. I just have seen the</p> <p>16 exhibit from Ms. Pier's testimony and Dr. Longo's</p> <p>17 report, but I don't have more information nor</p> <p>18 have I really sought it out about their</p> <p>19 credentials. I was just using it as pieces of</p> <p>20 information.</p> <p>21 Q. But again my question is: You have no</p> <p>22 ability or expertise on your own to judge whether</p> <p>23 Ms. Pier's testimony that there's not asbestos in</p> <p>24 talc is correct or Dr. Longo's testimony is</p> <p>25 correct. That's not an area of your expertise;</p>

<p style="text-align: right;">Page 322</p> <p>1 correct?</p> <p>2 A. It -- I wouldn't say I'm an expert in</p> <p>3 that area.</p> <p>4 Q. You mentioned earlier in response to</p> <p>5 Ms. Ahern's questions, you talked about heavy</p> <p>6 metals.</p> <p>7 Are you aware that IARC has not singled out</p> <p>8 a single heavy metal as a cause of ovarian</p> <p>9 cancer?</p> <p>10 A. Yes. I have seen that. I have</p> <p>11 reviewed the IARC monograph on heavy metals, and</p> <p>12 I'm aware.</p> <p>13 But, again, it's another sort of piece of</p> <p>14 the plausibility puzzle. If we -- we know that</p> <p>15 some of them are either listed as carcinogens or</p> <p>16 probable carcinogens. If they're in the talcum</p> <p>17 powder product, that's just another piece of the</p> <p>18 biological plausibility puzzle. And I --</p> <p>19 Q. Well, is it your -- I'm sorry. I</p> <p>20 didn't mean to cut you off.</p> <p>21 A. No. Sorry.</p> <p>22 Q. Is it your testimony that if something</p> <p>23 is considered a carcinogen for one organ system</p> <p>24 by IARC, that it's capable of causing cancer in</p> <p>25 all organ systems?</p>	<p style="text-align: right;">Page 324</p> <p>1 at the end of the answer before you started your</p> <p>2 next question.</p> <p>3 A. So I'm aware that they're in these</p> <p>4 things. What I'm looking at is a product that's</p> <p>5 used frequently and for -- in a lot of women for</p> <p>6 a long duration of time. So their exposure -- if</p> <p>7 they are in the talcum powder, their exposure to</p> <p>8 those heavy metals would be greater than the</p> <p>9 exposure they're getting in the environment.</p> <p>10 Q. Those same, exact heavy metals are in</p> <p>11 drinking water, bottled water, food, and</p> <p>12 multivitamins that people take every single day,</p> <p>13 and there's no evidence that they cause ovarian</p> <p>14 cancer; correct?</p> <p>15 A. There has not been a link with heavy</p> <p>16 metals to ovarian cancer specifically as of yet.</p> <p>17 Q. And there's no evidence you're aware of</p> <p>18 that the tissue levels of any heavy metals are</p> <p>19 higher in talc users than in women who never used</p> <p>20 talc; correct?</p> <p>21 A. I don't -- I'm not aware of that study</p> <p>22 being done.</p> <p>23 Are you talking tissue levels?</p> <p>24 Q. Blood levels --</p> <p>25 A. Blood levels.</p>
<p style="text-align: right;">Page 323</p> <p>1 A. As I've testified several times here</p> <p>2 today, I think different tissues respond in</p> <p>3 different ways to different carcinogens. So I</p> <p>4 would not make a blanket statement that a</p> <p>5 carcinogen in one site will definitely cause</p> <p>6 cancer in another site.</p> <p>7 However, having carcinogens, known</p> <p>8 carcinogens in a product, it can add to the</p> <p>9 biological plausibility. And we're not talking</p> <p>10 about these heavy metals sort of in the</p> <p>11 environment. I mean, these are -- there's</p> <p>12 evidence that they are in a product that's used</p> <p>13 regularly and frequently.</p> <p>14 Q. Are you -- are you aware that the same,</p> <p>15 exact heavy metals are in bottled drinking water?</p> <p>16 A. So, again, I don't know what the levels</p> <p>17 of these heavy metals are in drinking water. I</p> <p>18 know that they are found in the environment</p> <p>19 commonly.</p> <p>20 Q. Are you aware they're in foods?</p> <p>21 A. I'm aware that they are in the</p> <p>22 environment and foods regularly. Yes. But --</p> <p>23 Q. Are you aware they're in multivitamins?</p> <p>24 MR. ROTMAN: Wait. Wait.</p> <p>25 I was hearing a "but" and not a period</p>	<p style="text-align: right;">Page 325</p> <p>1 Q. -- tissue levels. Anything you want.</p> <p>2 You're -- there's no medical or scientific</p> <p>3 evidence that you would tell this court that the</p> <p>4 levels of heavy metals in women who use talcum</p> <p>5 powder in the genital area are higher than women</p> <p>6 who have never used talcum powder?</p> <p>7 A. I'm not aware of studies that have been</p> <p>8 done that have looked at the levels of those</p> <p>9 heavy metals in ovarian tissue or blood levels.</p> <p>10 Q. Earlier you mentioned there was a study</p> <p>11 about changing gene expression in the presence of</p> <p>12 talc in mesothelial cells?</p> <p>13 A. Yes.</p> <p>14 Q. The mere fact that you have changing</p> <p>15 gene expression in no way implies something is</p> <p>16 carcinogenic; correct?</p> <p>17 A. It -- it's evidence that it's changing</p> <p>18 gene expression within those cells, and --</p> <p>19 Q. If -- I'm sorry. Go ahead.</p> <p>20 A. And the genes in that study that had</p> <p>21 increased expression are involved in the</p> <p>22 inflammatory -- are pieces in the inflammatory</p> <p>23 response.</p> <p>24 Q. You're aware that many of those genes</p> <p>25 in that study were antioxidant genes and</p>

<p style="text-align: right;">Page 326</p> <p>1 anti-inflammatory genes that were elevated; 2 correct? 3 A. They can regulate or deregulate, and I 4 think it's interesting -- let's say that they 5 were antioxidant -- they were producing 6 antioxidant enzymes. I think that is evidence 7 that it's trying -- that the cell is trying to 8 respond and is trying to prepare itself for an 9 insult, an inflammatory insult. Otherwise, why 10 would that gene be expressed? 11 So, I mean, there's increased and decreased 12 regulation. 13 Q. But, Dr. Kane, you're aware that 14 strenuous exercise can increase gene expression 15 of prooxidants, antioxidants, proinflammatory, 16 anti-inflammatory proteins; correct? 17 A. Strenuous exercise can increase 18 antioxidants in proinflammatory, 19 anti-inflammatory proteins. 20 But, again, I'm opining about a product that 21 someone is going to be using regularly with 22 frequency over a long period of time. 23 Q. You're aware that -- 24 A. It just adds to the -- I'm not -- you 25 know, I don't have an opinion about whether or</p>	<p style="text-align: right;">Page 328</p> <p>1 MR. KLATT: Can we mark that? 2 MR. ROTMAN: Can we get a time check? 3 THE VIDEOGRAPHER: 6:30. 4 MR. ROTMAN: Thank you. 5 (Article entitled "Pycnogenol 6 reduces Talc-induced Neoplastic 7 Transformation in Human Ovarian Cell 8 Cultures" marked Exhibit 26.) 9 MS. AHERN: That's 26. 10 Q. Referring to Exhibit 26, Dr. Kane, is 11 this the Buz'Zard study you were mentioning 12 earlier? 13 A. Yes, this is it. 14 Q. And if you'll flip over to Page 3 -- 15 excuse me, 582, Figure 3, do you see Figure 3 16 is -- 17 MR. ROTMAN: Can I have a copy of that, 18 please? 19 MR. KLATT: I'm sorry? 20 MR. ROTMAN: I'm waiting for a copy of 21 that. 22 MR. KLATT: Oh. Yes. We do provide 23 copies. 24 MR. ROTMAN: This is Exhibit No. 1? 25 THE WITNESS: I'm sorry. Which table?</p>
<p style="text-align: right;">Page 327</p> <p>1 not those heavy metals are in talc. I've looked 2 at some evidence that they are there, but I don't 3 have an opinion that they're actually in talc. 4 It's just another piece of evidence, again, for 5 the biological plausibility. 6 Q. Well, you're not saying that people who 7 regularly engage in chronic exercise, chronic 8 strenuous exercise, for a long period of time are 9 at increased risk of cancer because they have 10 increased gene expression, are you? 11 A. Well, there hasn't been epidemiologic 12 evidence that is consistent that people who do 13 routine strenuous exercise get cancer. 14 Q. The Buz'Zard study you cited, that 15 actually showed that talc -- increasing doses of 16 talc decreased release of reactive oxygen species 17 from ovarian cells, not increased it; correct? 18 A. I believe it was different -- I would 19 have to look at the study, but it was over 20 different time periods. It fluctuated. 21 Q. The highest level of reactive oxygen 22 species in the Buz'Zard study was the group of 23 cells that had no talc applied at all; correct? 24 A. I'd have to re-review the study. 25 Q. Let's --</p>	<p style="text-align: right;">Page 329</p> <p>1 MS. AHERN: Twenty-six. 2 BY MR. KLATT: 3 Q. Figure 3. Page 582. 4 MR. ROTMAN: What exhibit are we on? 5 COURT REPORTER: Twenty-six. 6 MR. ROTMAN: Thank you. 7 BY MR. KLATT: 8 Q. And you see Figure 3 is "ROS." 9 That stands for reactive oxygen species? 10 A. That's -- 11 Q. And, by the way, ROS are generated by 12 every cell of the body every day, 24 hours a day; 13 correct? 14 A. Reactive -- you do see it in daily cell 15 life. But, again, I'm talking about an 16 additional exposure, an agent that that is being 17 applied in addition to what you're seeing on -- 18 basically the cell has, as we just discussed, 19 they have ways of mitigating reactive oxygen 20 species. 21 The cell can increase their antioxidant 22 enzymes, but at some point, they can get 23 overloaded. So if you're giving it a higher dose 24 at a higher frequency than those systems can 25 handle, you're going to have an increased risk of</p>

<p style="text-align: right;">Page 330</p> <p>1 mutagenesis.</p> <p>2 Q. Well, let's look at what Buz'Zard found</p> <p>3 when talc was applied to surface ovarian cells.</p> <p>4 Do you see that? That's Figure 3A up at the</p> <p>5 top?</p> <p>6 A. A, up at the top. Yes.</p> <p>7 Q. And you'll agree with me, you see on</p> <p>8 the Y axis it says "Percentage of reactive oxygen</p> <p>9 species generation in OSE2a cells"; correct?</p> <p>10 A. Yes.</p> <p>11 Q. That's ovarian surface epithelial</p> <p>12 cells; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And you'll see at the zero talc level</p> <p>15 on the X axis --</p> <p>16 A. Mm-hmm.</p> <p>17 Q. -- that had 100 percent talc -- excuse</p> <p>18 me -- a 100 percent reactive oxygen species</p> <p>19 generation at all three time periods; correct?</p> <p>20 A. That is correct. And --</p> <p>21 Q. And when talc was applied?</p> <p>22 MR. ROTMAN: Wait. Wait.</p> <p>23 Did you finish your answer?</p> <p>24 A. Well, we were just talking about how</p> <p>25 cells can have innate ROS generation.</p>	<p style="text-align: right;">Page 332</p> <p>1 generation for each talc microgram.</p> <p>2 Q. Do you see in the far right column,</p> <p>3 they applied 200 micrograms of hydrogen peroxide?</p> <p>4 A. Yes.</p> <p>5 Q. And that resulted in a 200 percent</p> <p>6 increase in reactive oxygen species during those</p> <p>7 time periods; correct?</p> <p>8 A. That is what it says. Yes.</p> <p>9 Q. And that's their positive control;</p> <p>10 correct?</p> <p>11 A. Let me just double-check.</p> <p>12 If I'm remembering the study correctly, yes,</p> <p>13 you are -- you are right.</p> <p>14 Q. People gargle with hydrogen peroxide;</p> <p>15 correct?</p> <p>16 A. They shouldn't.</p> <p>17 Q. Well, you know, it's allowed on the</p> <p>18 bottle.</p> <p>19 You know that; correct?</p> <p>20 A. If you're telling me they gargle with</p> <p>21 it, that's fine.</p> <p>22 Q. Well, they put it on cuts; right?</p> <p>23 A. They shouldn't put it on cuts. It's</p> <p>24 actually --</p> <p>25 Q. It's sold for that, isn't it?</p>
<p style="text-align: right;">Page 331</p> <p>1 Q. And this graph shows that as you</p> <p>2 applied increasing doses of talc, the level of</p> <p>3 generation of reactive oxygen species in the</p> <p>4 ovarian cells went down.</p> <p>5 It didn't go up; correct?</p> <p>6 A. Well, it goes up at -- what's the 50 --</p> <p>7 the 50 micrograms per milliliter. It goes up at</p> <p>8 that dose at the 120 hour, and then it goes up at</p> <p>9 the 200 microgram level.</p> <p>10 Q. That's not talc, is it?</p> <p>11 A. I'm sorry. I'm looking at -- I'm</p> <p>12 looking at -- it says "Talc micrograms per</p> <p>13 milliliter," and then it lists the different</p> <p>14 hours on the right; that they're color-coded to</p> <p>15 the different hours.</p> <p>16 Q. And 17 out of the 18 measurements they</p> <p>17 took when talc is applied to ovarian cells showed</p> <p>18 the ovarian cells generated less reactive oxygen</p> <p>19 species than no talc at all; correct?</p> <p>20 A. And I --</p> <p>21 Q. Is that correct?</p> <p>22 A. It looks like at different periods of</p> <p>23 time at the 100 micrograms and 500, there was</p> <p>24 less than the lower. But I'm not sure what the</p> <p>25 threshold dose would be for optimal ROS</p>	<p style="text-align: right;">Page 333</p> <p>1 A. I think most MDs would tell you that</p> <p>2 it's probably better not to use hydrogen peroxide</p> <p>3 on open cuts because it can cause a pretty severe</p> <p>4 reaction.</p> <p>5 Q. You're aware that it's sold over the</p> <p>6 counter in stores every day for -- as an</p> <p>7 antiseptic?</p> <p>8 A. Talcum powder is sold for everyday use</p> <p>9 on babies.</p> <p>10 Q. So are you telling us that hydrogen</p> <p>11 peroxide now causes cancer?</p> <p>12 A. I'm saying that it will release ROS</p> <p>13 species generation.</p> <p>14 Q. Far more than talc; correct?</p> <p>15 A. Based on this study, it appears that</p> <p>16 way.</p> <p>17 Q. And you --</p> <p>18 A. This one study.</p> <p>19 Q. You agree with me this shows, as you</p> <p>20 apply talc, reactive oxygen species in ovarian</p> <p>21 cells decreases.</p> <p>22 It doesn't increase at 17 out of 18 time</p> <p>23 points; correct?</p> <p>24 A. They're -- I will agree with you,</p> <p>25 except there is a time point where it is</p>

<p style="text-align: right;">Page 334</p> <p>1 increased. And I don't know -- my caveat is I 2 don't know where the threshold would be where the 3 ROS would stop being generated. 4 Q. Is aspirin approved by any 5 pharmaceutical company or recommended by any 6 medical organization for prevention of ovarian 7 cancer? 8 A. That is not on the label description. 9 Q. If aspirin prevented ovarian cancer, 10 don't you think it would be marketed for that 11 purpose? 12 MR. TISI: Objection. 13 MR. ROTMAN: Objection. 14 A. I'm sure it may be after years of FDA 15 red tape and approval, but the literature -- 16 again, I've said the literature is not as beefy 17 as the epi data when we're looking at aspirin and 18 NSAIDs. 19 NSAID, in particular, is not as consistent. 20 The aspirin data does appear to be consistent in 21 lowering the risk, but there are not a lot of 22 studies looking at this yet. 23 Again, though, just a piece of the puzzle 24 for a biologic plausibility. 25 Q. Well, certainly, we're not at the point</p>	<p style="text-align: right;">Page 336</p> <p>1 A. I have to look at the studies. There 2 might be one where it wasn't statistically 3 significant, but I think the majority of the ones 4 that looked at aspirin use showed a decreased 5 risk of ovarian cancer. 6 Q. Are you -- are you a member of the 7 International Society of Gynecologic 8 Pathologists? 9 A. I don't think I'm a member currently. 10 No. 11 Q. Have you ever been? 12 A. I believe so. 13 Q. It's not on your CV. 14 A. Okay. I'm not currently. I know that. 15 Q. Are you a member of the American 16 Society of Clinical Pathology? 17 A. I actually am. 18 Q. It's not on your CV. 19 A. Okay. That should be updated, then. 20 Q. Have you ever been a member of any 21 working group or organization on the 22 classification of female reproductive organ 23 tumors? 24 A. No. I can't -- no. 25 Q. You mentioned the Surgeon General's</p>
<p style="text-align: right;">Page 335</p> <p>1 for aspirin and ovarian cancer that we are, for 2 example, with aspirin in terms of cardiovascular 3 risk; correct? 4 A. I would agree with that sentiment. 5 Q. And doctors and medical organizations 6 have recommended aspirin for reduction of 7 cardiovascular risk; correct? 8 A. That's correct. Although the dosage 9 has -- as of late, they're kind of parsing out 10 the -- they're reevaluating what dosages, but 11 you're correct. 12 Q. And you can't cite a single medical 13 organization that at this point in time says the 14 evidence that aspirin reduces ovarian cancer is 15 sufficient that women should take it on a regular 16 basis to reduce ovarian cancer; correct? 17 A. Well, I think I've said there aren't 18 that many studies yet. It's only -- that I'm 19 aware of, there are only a handful. They've been 20 consistent with aspirin. Not so much with NSAID. 21 That's, I think, as far as the evidence takes us 22 as this point. 23 Q. There's actually studies showing that 24 chronic aspirin ingestion doesn't decrease 25 ovarian cancer risk; correct?</p>	<p style="text-align: right;">Page 337</p> <p>1 report in 1964. You're aware that when that came 2 out about smoking, there were numerous studies in 3 the literature at that point in time showing that 4 the chemicals in cigarette smoke actually damaged 5 DNA and resulted in cancer; it wasn't based just 6 on epidemiology? 7 A. I think epidemiology -- my point was 8 that the epidemiology was the sort of first -- 9 there were pathologists that had noticed on 10 autopsies in patients that smoked -- it was 11 actually pathologists and a surgeon in the early 12 years -- that had noticed some changes, some 13 squamous metaplastic changes. 14 But it was really the epi data that sort of 15 drove the research on smoking and tobacco 16 initially. But, again, there were some studies 17 that had shown some pathologic changes in 18 smokers. That's true. 19 Q. You're aware that the cohort studies, 20 the hospital-based case-control studies, and the 21 population-based case-control studies all 22 uniformly showed that smoking increased the risk 23 of lung cancer; correct? 24 A. That's correct. 25 Q. And that's not true for talc and</p>

<p style="text-align: right;">Page 338</p> <p>1 ovarian cancer; correct?</p> <p>2 A. Well, I have some issues with the</p> <p>3 cohort studies.</p> <p>4 Q. I know that.</p> <p>5 But my statement is true; correct?</p> <p>6 A. But I think it's relevant because the</p> <p>7 cohort studies, I don't believe, followed</p> <p>8 patients for a long enough time.</p> <p>9 The Nurses' Health Study only asked about</p> <p>10 talcum powder use once in 1982, so there's</p> <p>11 certainly room for misclassifications of users as</p> <p>12 never users.</p> <p>13 And some of -- some of -- again, there's</p> <p>14 smaller numbers because it's a -- it's a cohort</p> <p>15 study.</p> <p>16 Q. You're aware that the National Cancer</p> <p>17 Institute doesn't agree with you on that, aren't</p> <p>18 you?</p> <p>19 A. I have seen the NCI website. I</p> <p>20 certainly considered what they say about it. I</p> <p>21 don't know if they have done the same type of</p> <p>22 analysis as I've done. I don't believe it's on</p> <p>23 their website what methodology they used and what</p> <p>24 literature they reviewed.</p> <p>25 So I'm aware of what they've stated. But,</p>	<p style="text-align: right;">Page 340</p> <p>1 that one statement.</p> <p>2 Go ahead.</p> <p>3 MR. ROTMAN: If you want to do that,</p> <p>4 that's fine.</p> <p>5 BY MR. KLATT:</p> <p>6 Q. That draft -- Health Canada issued a</p> <p>7 draft assessment that's undergoing a 60-day</p> <p>8 public comment period; correct?</p> <p>9 A. That's true.</p> <p>10 Q. And then they have up to two years to</p> <p>11 decide whether to take any action or no action at</p> <p>12 all; correct?</p> <p>13 A. Well, there's two pieces of that. From</p> <p>14 my understanding is that they've already done the</p> <p>15 scientific. They've already done the literature</p> <p>16 review. They've already done their Bradford Hill</p> <p>17 analysis, and they've come to the conclusion that</p> <p>18 they've come to.</p> <p>19 And then there's the public commentary. And</p> <p>20 then there's the regulatory aspect of it.</p> <p>21 Now, I am -- I would not claim to be an</p> <p>22 expert in regulatory. I know we have regulatory</p> <p>23 experts that are coming on. But in -- from my</p> <p>24 understanding, the regulatory aspect is different</p> <p>25 than the scientific aspect.</p>
<p style="text-align: right;">Page 339</p> <p>1 you know, I've still done this extensive review</p> <p>2 that I'm not sure they did to come to my</p> <p>3 conclusion.</p> <p>4 Q. You honestly don't know what the NCI</p> <p>5 did in terms of review to come to their</p> <p>6 conclusion, do you?</p> <p>7 A. They didn't state what they did, so I</p> <p>8 do not know. So that would -- but that's</p> <p>9 something that I'm thinking about when I'm taking</p> <p>10 into consideration.</p> <p>11 Q. And you are aware that they just</p> <p>12 updated their statement that the evidence does</p> <p>13 not support a link between talc and ovarian</p> <p>14 cancer in January 2019, the same month we're</p> <p>15 sitting here today?</p> <p>16 A. I don't know if I've gone to the NCI</p> <p>17 website this month.</p> <p>18 But I'm also aware of Health Canada that</p> <p>19 came out and did -- and we know what the</p> <p>20 methodology and literature they -- they spelled</p> <p>21 it out very clearly what their methodology was,</p> <p>22 what literature review they did, and they came to</p> <p>23 the same conclusion that I did.</p> <p>24 MR. ROTMAN: Off the record, Mike?</p> <p>25 MR. KLATT: Let me just follow up on</p>	<p style="text-align: right;">Page 341</p> <p>1 MR. ROTMAN: Mike, you're done? I just</p> <p>2 want to --</p> <p>3 MR. KLATT: I'm through.</p> <p>4 MR. ROTMAN: I just want to go off the</p> <p>5 record.</p> <p>6 We're done with seven hours.</p> <p>7 MR. KLATT: Yes. I'm done.</p> <p>8 MR. TISI: Let's take a minute.</p> <p>9 THE VIDEOGRAPHER: Off the record,</p> <p>10 6:31 p.m.</p> <p>11 (A recess was taken.)</p> <p>12 THE VIDEOGRAPHER: Back on the record,</p> <p>13 6:40 p.m.</p> <p>14 CROSS-EXAMINATION</p> <p>15 BY MR. ROTMAN:</p> <p>16 Q. Dr. Kane, I know it's been a long day</p> <p>17 for you, but I'm going to ask you a few</p> <p>18 questions. I will be brief.</p> <p>19 A. Okay.</p> <p>20 Q. At one point today, you were asked some</p> <p>21 questions by Attorney Ahern about certain</p> <p>22 negative studies on inflammation, and she</p> <p>23 mentioned Bonovast 2005 and Ni 2012, which she</p> <p>24 asked you about.</p> <p>25 Do you recall that?</p>

<p style="text-align: right;">Page 342</p> <p>1 A. Yes.</p> <p>2 Q. She did not show you those studies, did</p> <p>3 she?</p> <p>4 A. I don't believe I saw them.</p> <p>5 Q. Are you able to agree with her</p> <p>6 characterization that these were negative studies</p> <p>7 without having -- without looking at them?</p> <p>8 A. I should have asked for them and had</p> <p>9 them in front of me while asking questions.</p> <p>10 Q. Now, you were asked questions --</p> <p>11 A. I mean answering questions.</p> <p>12 Q. -- throughout the day about</p> <p>13 inflammation as a biologically plausible</p> <p>14 mechanism for explaining talc causing ovarian</p> <p>15 cancer in light of the epi study findings.</p> <p>16 A. Yes.</p> <p>17 Q. You were also asked questions about</p> <p>18 cigarette smoking at various times throughout the</p> <p>19 day?</p> <p>20 A. Yes.</p> <p>21 Q. Does cigarette smoking have an</p> <p>22 inflammatory effect?</p> <p>23 A. Yes.</p> <p>24 Q. What is the --</p> <p>25 A. It does cause chronic inflammation.</p>	<p style="text-align: right;">Page 344</p> <p>1 just strike that.</p> <p>2 You were asked questions about surgical</p> <p>3 gloves and surgical-grade talc on surgical</p> <p>4 gloves.</p> <p>5 A. Yes.</p> <p>6 Q. Do you recall that?</p> <p>7 A. Yes.</p> <p>8 Q. And I think you were asked if you were</p> <p>9 aware of any studies linking the use of talcum</p> <p>10 powder on surgical gloves with the occurrence of</p> <p>11 ovarian cancer.</p> <p>12 Do you recall that?</p> <p>13 A. Yes.</p> <p>14 Q. Is there a difference, a notable</p> <p>15 difference, between talcum powder on surgical</p> <p>16 gloves and the talcum powder products in perineal</p> <p>17 use that, regardless of the constituent of the</p> <p>18 powder, that you would want to point out?</p> <p>19 MR. KLATT: Objection. Form.</p> <p>20 MS. AHERN: Same.</p> <p>21 A. So a patient's exposure to surgical</p> <p>22 gloves are going to be infrequent and not of long</p> <p>23 duration. It's not the same type of exposure as</p> <p>24 regular and frequent application of perineal</p> <p>25 talcum powder that we're seeing in the epi data.</p>
<p style="text-align: right;">Page 343</p> <p>1 Q. You were also asked questions about</p> <p>2 heavy metals being present in food and water and</p> <p>3 vitamins; correct?</p> <p>4 A. I remember. Yeah.</p> <p>5 Q. Do -- what is different between those</p> <p>6 circumstances and the situation that we have been</p> <p>7 discussing all day today involving talcum powder?</p> <p>8 A. With talcum powder, we do have the epi</p> <p>9 data that are consistent and show an increased</p> <p>10 risk of ovarian cancer with talcum powder use.</p> <p>11 Q. And with respect -- you were asked some</p> <p>12 questions in relation to the Buz'Zard study about</p> <p>13 hydrogen peroxide and the reactive oxygen species</p> <p>14 reaction?</p> <p>15 A. Yes.</p> <p>16 Q. Are you aware of any evidence that</p> <p>17 hydrogen peroxide -- the effect of hydrogen</p> <p>18 peroxide in the female genital tract?</p> <p>19 A. I'm not aware that women routinely use</p> <p>20 hydrogen peroxide in the female genital tract.</p> <p>21 Q. And is there anything in particular</p> <p>22 about the -- that part of the anatomy that where</p> <p>23 certain agents, exposure to certain agents, would</p> <p>24 raise any particular concerns -- strike that.</p> <p>25 I think that was a bad question, so I'll</p>	<p style="text-align: right;">Page 345</p> <p>1 MR. ROTMAN: No further questions.</p> <p>2 It's 6: --</p> <p>3 (Discussion off the record.)</p> <p>4 MR. ROTMAN: You're right.</p> <p>5 BY MR. ROTMAN:</p> <p>6 Q. I have some questions for you about</p> <p>7 your testimony on the Harlow paper.</p> <p>8 A. Okay.</p> <p>9 Q. Can you pull that out in front of you,</p> <p>10 which was Exhibit 20?</p> <p>11 A. Okay.</p> <p>12 Q. Can you turn to Table 3.</p> <p>13 A. Okay.</p> <p>14 Q. And do you recall that you were asked</p> <p>15 questions about dose-response in this study?</p> <p>16 A. Yes.</p> <p>17 Q. And do you recall that you were</p> <p>18 specifically asked questions about this Table 3?</p> <p>19 A. Yes.</p> <p>20 Q. Could you look at the middle part of</p> <p>21 Table 3, at the column with "adjusted odds</p> <p>22 ratios"?</p> <p>23 A. Yes.</p> <p>24 Q. What can -- what do you observe with</p> <p>25 respect to the adjusted odds ratio as the -- as</p>

<p style="text-align: right;">Page 346</p> <p>1 the -- as the number of applications goes from 2 less than 1,000 to greater than 10,000? 3 A. The adjusted ORs go from -- the null, 4 1.0 at none, 1.4 at less than 1,000, to 1.7 at 5 greater than 10,000. 6 Q. And so what, just looking at the 7 adjusted odds ratio, what -- 8 A. It's an increase with increased -- 9 Q. -- what is your takeaway? 10 A. So it does show an increased odds ratio 11 with increased applications. 12 The confidence intervals do include the 13 null, but they're -- the higher end, it's higher 14 confidence interval at the upper end. 15 And it's not very far from the null on the 16 lower end. 17 And it, in fact, includes -- it's 1.0 at 18 greater than 10,000. 19 Q. And so for the 1,000 to 10,000 20 applications, the lower bound of the confidence 21 interval is .9? 22 A. Correct. 23 Q. And how close is that to being a 24 statistically significant finding? 25 A. Very close.</p>	<p style="text-align: right;">Page 348</p> <p>1 A. Yes. 2 Q. And this is -- this is in the 3 "Discussion" section of the paper; is that right? 4 A. Yes. 5 Q. And do you see in the paragraph that 6 I'm pointing to that begins with "Our study"? 7 A. Yes. 8 Q. Could you read into the record and 9 comment on the last sentence in that paragraph. 10 A. "Daily versus less-than-daily talc use 11 and talc use for more than ten years versus less 12 than ten years were associated with greater risk 13 for ovarian cancer." 14 Q. And can you comment on that? 15 A. So that does show a trend for a 16 dose-response. 17 MR. ROTMAN: Okay. So I have 6:48. 18 You've got eight minutes. 19 RE CROSS-EXAMINATION 20 BY MR. KLATT: 21 Q. That Harlow study you were just looking 22 at -- 23 A. Yeah. 24 Q. -- is that the 1992 Harlow study? 25 A. It's the 1992 from Exhibit 20.</p>
<p style="text-align: right;">Page 347</p> <p>1 Q. And can you also take a look at the 2 discussion on that page in the left-hand column 3 in the paragraph that begins with "We also 4 examined"? 5 A. Okay. 6 Q. Is there a discussion in that paragraph 7 concerning the author's discussion of 8 dose-response? 9 A. Yeah. There's a sentence that states, 10 "The categorical analysis showed that relative to 11 nonusers, the risk was greatest in women who 12 applied talc at least once per day. When years 13 of use was included as a continuous variable, the 14 test for linear trend was 3.32, p-value of .07. 15 "The categorical analysis show that relative 16 to nonusers, women who applied talc for more than 17 ten years were at a 60 percent greater risk for 18 ovarian cancer. Likewise, perineal applications 19 of talc early in life, before age 20, or 20 applications within six months of diagnosis 21 reference age for controls produced the stronger 22 ORs." 23 Q. And I'd like to also call your 24 attention to the page 24 in the right-hand 25 column.</p>	<p style="text-align: right;">Page 349</p> <p>1 Q. And can you look on the last page of 2 this study, the page where the article ends and 3 the reference begins. 4 Did Harlow find the strength of association 5 between genital use of talc and ovarian cancer 6 was strong or weak? 7 A. So they use -- they say, "Because the 8 overall association between genital use of talc 9 and ovarian cancer remains weak." 10 And, again, "weak" is sort of a relative. 11 I've seen weak to moderate with this odds ratio. 12 And this is also 1992. 13 MR. KLATT: Object. Nonresponsive. 14 Q. I'm simply asking you, Dr. Kane, does 15 Harlow say strength of association between 16 ovarian cancer and talc use is strong or weak? 17 A. Well, I'm putting it in context. He 18 states -- I agree with you that's what the words 19 say, but I'm putting it in context in that "weak 20 to moderate" is used amongst epidemiologists for 21 this level of overall risk. 22 And this is 1992, so there wasn't the 23 subsequent studies that have gone on that show 24 consistent, similar overall risk odds ratio. 25 Q. And would it be correct that the</p>

<p style="text-align: right;">Page 350</p> <p>1 statement that I asked you to read says in full, 2 "Because the overall association between genital 3 use of talc and ovarian cancer remains weak, it 4 is unlikely that this exposure disease pathway is 5 the principal one involved in ovarian cancer 6 etiology"? 7 Is that what Harlow said? 8 A. That's what it states. But, again, 9 that is 1992. This is the very beginning of the 10 epi data looking at this exposure and ovarian 11 cancer. 12 MR. KLATT: Object and move to strike 13 everything after "That's what it says." 14 Q. And, by the way, the odds ratio that 15 Harlow found overall was 1.5. 16 And that's even a little higher than the 17 odds ratios the more recent meta-analyses have 18 shown; correct? 19 A. So -- 20 Q. So they're even weaker than Harlow. 21 A. I'm sure some epidemiologists might 22 take -- I'm not -- but, again, I've seen, even 23 with 1.3 and 1.4, epidemiologists refer to that 24 as "moderate." 25 So I don't know if it's semantics, but it's</p>	<p style="text-align: right;">Page 352</p> <p>1 element of recall bias in case-control studies, 2 but the authors are aware. Many of them talk 3 about that and discuss why they feel recall bias 4 wasn't an explanation. 5 And, again, we're talking about multiple 6 studies over numerous populations over different 7 periods of time, most of them well before the 8 general public knew about an association between 9 talcum powder and ovarian cancer. 10 And even further, the fact that there's a 11 strong association in the literature with serous 12 invasive cancer would argue against a recall bias 13 because the lay public is not knowledgeable about 14 the histologic subtypes of epithelial ovarian 15 carcinoma. 16 Q. Let me ask you this, Dr. Kane: We 17 lawyers, before we have to go to trial, like to 18 know if the prospective jurors have already made 19 up their mind about the case. 20 Do you know if in any of these case-control 21 studies where the women who had ovarian cancer, 22 were they asked before they entered the study, 23 "Do you have a preconceived notion about what 24 caused your ovarian cancer?" 25 A. I'm not aware of a case-control design</p>
<p style="text-align: right;">Page 351</p> <p>1 1.3. It's a 30 percent increased risk. In this 2 case, 1.5, a 50 percent increase in risk. And in 3 a rare disease like ovarian cancer, that's 4 significant. 5 Q. And Harlow calls a 1.5 odds ratio weak; 6 correct? 7 A. That's what he says in this 1992 paper. 8 Q. And you'd agree with me the more recent 9 meta-analyses of talc and ovarian cancer have a 10 lower odds ratio than 1.5? 11 A. They seem to be between 1.3 and 1.4, 12 but the important thing to me is the consistency. 13 Q. And you're aware that epidemiologists 14 say with case-control studies that odds ratios in 15 the range of 1.0 to 1.5 are well within the range 16 that can be explained by bias and confounding? 17 MR. ROTMAN: Objection. 18 A. I think all of the studies were 19 aware -- all of the authors were aware of 20 potential recall bias and confounding and sought 21 to control as much as possible those factors in 22 their control studies. Most of them, I feel, 23 were relatively well-designed to assess for and 24 adjust for multiple confounding factors. 25 And as far as recall bias, there's an</p>	<p style="text-align: right;">Page 353</p> <p>1 that would ask that question because even asking 2 that question would potentially add an element of 3 recall bias -- 4 Q. But if a woman already -- 5 MR. TISI: She wasn't finished. 6 Q. Were you finished? 7 A. I was going to say in a lot of these 8 studies, they also asked about smoking history 9 and other potential lifestyle issues in addition 10 to talcum powder use that would -- and yet, those 11 types of questions didn't show an elevated risk 12 like talcum powder products. 13 Q. Well, wouldn't you want to know -- 14 before you interviewed the women who have ovarian 15 cancer, wouldn't you want to know if they have a 16 preconceived notion about what caused their 17 ovarian cancer so if you didn't exclude them from 18 the study, at least you could take that 19 preconceived bias into account when you did the 20 statistics? 21 A. I would think if you're designing a 22 case-control study and trying to avoid recall 23 bias, there are better ways to do that because 24 just by asking, "Do you have a preconceived 25 notion about it?", you're introducing potential</p>

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1 bias because they might think, Oh, maybe there is
 2 an association. And you're adding bias,
 3 potentially, that way.
 4 Q. You mentioned cigarette smoking just a
 5 minute ago in response to Mr. Rotman's questions.
 6 And you said cigarette smoking involves a
 7 chronic inflammatory condition in the body;
 8 correct?
 9 A. There is an inflammatory response in
 10 the body.
 11 Q. But cigarette smoking has not been
 12 shown to increase the risk of the two most common
 13 forms of ovarian cancer, which is serous invasive
 14 and endometrioid invasive; correct?
 15 A. So, again, different tissues will
 16 respond to different agents in different ways.
 17 Mucinous carcinoma has been associated in some
 18 studies with smoking, so there is evidence that
 19 epithelial ovarian cancer can be caused by
 20 smoking.
 21 MR. KLATT: Object. Nonresponsive.
 22 Q. The two most common forms of invasive
 23 ovarian cancer -- serous, which is the most
 24 common, and endometrioid, which is the second
 25 most common -- have not been shown to be elevated

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1 as a result of smoking; correct?
 2 A. The data has not shown an association
 3 between those two types with smoking.
 4 Q. Even though smoking involves a chronic
 5 inflammatory state; correct?
 6 A. But, again --
 7 Q. That is -- did you hear my question?
 8 Even though smoking involves a chronic
 9 inflammatory state; correct?
 10 A. We're talking about different types of
 11 exposures.
 12 Q. Does smoking --
 13 A. Different agent --
 14 MR. ROTMAN: One second, Mike.
 15 Do you want an answer to the question?
 16 Because you're cutting --
 17 BY MR. KLATT:
 18 Q. My question is: Does smoking
 19 involve --
 20 MR. ROTMAN: Wait. Wait, Mike. Let
 21 her answer the question, and then you're done
 22 because we're over.
 23 Do you know what the question was?
 24 A. Does smoking involve an inflammatory
 25 state?

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1 Yes. It involves an inflammatory state.
 2 MR. KLATT: Thank you, Doctor.
 3 MR. TISI: Just one question.
 4 (Discussion off the record.)
 5 MR. ROTMAN: We're done.
 6 MR. TISI: Thank you.
 7 THE VIDEOGRAPHER: Here ends today's
 8 deposition. Off the record, 6:58 p.m.
 9 (Deposition concluded at 6:58 p.m.)
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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
 hereby certify that I have read the
 foregoing pages, and that the same
 is a correct transcription of the answers
 given by me to the questions therein
 propounded, except for the corrections or
 changes in form or substance, if any,
 noted in the attached Errata Sheet.

 SARA H E. KANE, M.D. DATE

Subscribed and sworn
 to before me this
 _____ day of _____, 20____.

My commission expires: _____

 Notary Public

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C E R T I F I C A T E
 COMMONWEALTH OF MASSACHUSETTS
 SUFFOLK, SS.

I, Janet M. Sambataro, a Registered Merit
 Reporter and a Notary Public within and for the
 Commonwealth of Massachusetts do hereby certify:

THAT SARA H E. KANE, M.D., the witness whose
 testimony is hereinbefore set forth, was duly sworn
 by me and that such testimony is a true and accurate
 record of my stenotype notes taken in the foregoing
 matter, to the best of my knowledge, skill and
 ability; that before completion of the deposition
 review of the transcript was requested.

I further certify that I am not related to any
 parties to this action by blood or marriage; and that
 I am in no way interested in the outcome of this
 matter.

IN WITNESS WHEREOF, I have hereunto set my hand
 this 28th day of January, 2019.

 JANET M. SAMBATARO

Notary Public

My Commission Expires:
 July 16, 2021

Exhibit 140

WEILL CORNELL MEDICAL COLLEGE CURRICULUM VITAE FORM

(REQUIRED FORMAT)

Signature (required):	<i>Karla V. Ballman</i>
Version date:	5 June 2018

A. GENERAL INFORMATION

Required Information:

Name: First, Middle, Last	Karla V. Ballman
Office address:	Healthcare Policy and Research LA-225 Weill Cornell Medical College 402 East 67 th Street New York, NY 10065
Office telephone:	646-962-8023
Office fax:	646-962-0281
Home address:	430 East 63 rd Street Apt. 12G New York, NY 10065
Home telephone:	507-301-3013
Cell phone:	507-301-3013
Beeper:	N/A
Work Email:	kab2053@med.cornell.edu
Personal Email:	kvballman@gmail.com
Citizenship:	USA
If not a U.S. Citizen, do you have:	Immigrant visa (green card)? Non-immigrant Visa? Type:

Optional Information (not required but helpful):

Birth date:	11/14/1960
Birth place:	St. Cloud, MN

Marital status:	Divorced
Race/Ethnicity:	Caucasian

B. EDUCATIONAL BACKGROUND

1. Academic Degree(s): B.A. and higher; institution name and location; dates attended; date of award. Expand the table as needed.

Degree (abbreviation)	Institution Name and Location	Dates attended	Year Awarded
B.A.	Macalester College St. Paul, MN	9/1979 to 5/1983	1983
Scientiæ Magister (S.M.)	Massachusetts Institute of Technology Cambridge, MA	9/1985 to 6/1991	1989
Ph.D.	Massachusetts Institute of Technology Cambridge, MA	9/1985 to 6/1991	1991

2. Post-doctoral training (include residency/fellowships): In chronological order beginning with post-doctoral training positions; include full titles, ranks and inclusive dates held. Expand the tables as needed.

N/A

3. Continuing Medical Education Courses/Certificates

N/A

4. Other Educational Experiences

N/A

C. LICENSURE, BOARD CERTIFICATION, MALPRACTICE

1. Licensure: Every physician appointed to the Hospital staff, except interns, and aliens in the US via non-immigrant visas, must have a New York State license or a temporary certificate in lieu of the license.

N/A

2. Board Certification

N/A

3. Malpractice Insurance

N/A

D. PROFESSIONAL POSITIONS AND EMPLOYMENT

1. Academic positions (teaching and research)

Title	Institution name and location	Dates held
Assistant Professor of Mathematics and Computer Science	Macalester College St. Paul, MN	8/1991 to 6/1999
Lecturer of Statistics	University of Auckland Auckland, New Zealand	1/1994 to 7/1996
Assistant Professor of Biostatistics	Mayo Clinic College of Medicine Rochester, MN	12/1999 to 7/2001
Associate Professor of Biostatistics	Mayo Clinic College of Medicine Rochester, MN	7/2001 to 10/2007
Adjunct Associate Professor of Biostatistics	University of Minnesota Minneapolis, MN	9/2007 to 7/2015
Adjunct Associate Professor	Biomedical Informatics and Computation Biology, University of Minnesota Rochester Rochester, MN	9/2010 to 7/2015
Professor of Biostatistics	Mayo Clinic College of Medicine	11/2014 to 7/2015
Professor of Healthcare Policy and Research Tenure awarded (11/2016)	Weill Cornell Medical College New York, NY	7/2015 to present

2. Hospital positions (e.g., attending physician)

N/A

3. Other Employment

Title	Institution name and location	Dates held
Actuarial Trainee	Minnesota Mutual Life Insurance Company St. Paul, MN	1983 to 1985
Consultant	AT&T Bell Labs Software Production Research Naperville, IL	1991 to 1994
Research Associate	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	1999 to 2002
Senior Research Associate	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2002 to 2004
Senior Associate Consultant	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2004 to 2007

Senior Associate Consultant	Division of Biomedical Informatics Department of Health Sciences Research, Mayo Clinic Rochester, MN	2005 to 2007
Group Statistician	American College of Surgeons Oncology Group (ACOSOG) Statistics and Data Center Rochester, MN	2006 to 2014
Chair	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2006 to 2008
Consultant	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2007 to 2008
Consultant	Division of Biomedical Statistics and Informatics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2008 to 2015
Associate Editor	Journal of Clinical Oncology	2010 to 2017
Deputy Editor	Journal of Clinical Oncology	2017 to present
Consultant	Department of Surgery, Mayo Clinic Rochester, MN	2012 to 2015
Director of Biostatistics	Alliance Statistics and Data Center Rochester, MN	2013 to 2015
Division Chief of Biostatistics and Epidemiology	Healthcare Research and Policy Weill Cornell Medical College New York, NY	07/2015 to present

E. EMPLOYMENT STATUS (current or anticipated)

Name of Employer(s): Weill Cornell Medical College
Employment Status (choose one, delete the others): Full-time salaried by Weill Cornell

F. INSTITUTIONAL/HOSPITAL AFFILIATION

N/A

G. PERCENT EFFORT AND INSTITUTIONAL RESPONSIBILITIES

WCMC ANTICIPATED % EFFORT	(%)	Does the activity involve WCMC students/researchers? (Yes/No)
TEACHING	20%	yes
CLINICAL	0%	
ADMINISTRATIVE	40%	no
RESEARCH	40%	yes
TOTAL	100%	

INSTITUTIONAL RESPONSIBILITIES

1. **Teaching** (e.g., specific teaching functions, courses taught, dates: For guidance refer to **Teaching Metrics** table. Report your teaching activities in the 4 areas of teaching shown below. To provide a more detailed teaching report, use the **Teaching Activities Report** template or **Educator Portfolio** template (strongly encouraged). Refer to it here as an attachment (e.g., see attached), and attach it to the CV.

Didactic teaching: (e.g., lectures, continuing medical education courses, grand rounds, professional development programs, seminars, tutorials)	
Protocol Development (tutorial leader, Mayo Clinic College of Medicine) Health Sciences Grand Rounds	Dates 2008-2012
Mentorship: (e.g., mentor for medical student, graduate student, resident, clinical or postdoctoral research fellow or junior faculty projects; service as graduate student thesis advisor or committee member)	
8 M.S. candidates in the Clinical Research Master's degree program (Mayo Clinic College of Medicine)	Dates 2004-2015
Served on five M.S. thesis committees for M.S. candidates in the Clinical Research Master's degree program (Mayo Clinic College of Medicine)	2004-2015
Thesis advisor to 4 students in the Biomedical Informatics and Computational Biology M.S. degree program	2012-2015
Clinical teaching: (e.g., teaching in the clinic or hospital including bedside teaching, teaching in the operating room, preceptor in clinic)	
	Dates
Administrative teaching leadership role: (e.g., residency or fellowship director, course or seminar director or co-director)	
Probability and Mathematical Statistics (course director, Macalester College)	Dates 1991
Introductory Statistics (course director, Macalester College)	1991, 1992
Mathematical Modeling (course director, Macalester College)	1991, 1992
Calculus II (course director, Macalester College)	1992
Calculus III (course director, Macalester College)	1992
Applied Probability (course director, Macalester College)	1992, 1993, 1996, 1998
Data Analysis and Statistics	

Mathematical Statistics	1993, 1994, 1996, 1997, 1998
Stochastic Methods in Management Science (course director, University of Auckland)	1993, 1997, 1999
Decision Analysis (course director, University of Auckland)	1994, 1995
Data Analysis with R (course director, University of Auckland)	1994
Statistics Minor Curriculum Development (Macalester College)	1994, 1995
Elementary Statistics (course director, Macalester College)	1995-1996
Linear Algebra (course director, Macalester College)	1996, 1997, 1998
Senior Capstone (course director, Macalester College)	1996
Applied Multivariate Statistics (course director, Macalester College)	1997, 1998
Differential Equations (course director, Macalester College)	1998
Experimental Design and Data analysis (course director, Macalester College)	1998
Introductory Statistical Method I (course director, Mayo Clinic College of Medicine)	1998
Special Topics in Health Sciences Research (course director, Mayo Clinic College of Medicine)	1999
Introductory Statistics Methods II (course director, Mayo Clinic College of Medicine)	2000-2003
Clinical Trials (course director, Mayo Clinic College of Medicine)	2002, 2005
Introduction to Biostatistics (course director, Executive MBA/MS program, Weill Cornell Medicine)	2003-2004
	2010, 2011
	2017-Present

2. Clinical care (duties, dates): To document clinical activities use the table below or, to document extensive clinical activities use the [Clinical Portfolio template](#) (strongly encouraged). Refer to it here as an attachment and attach it to the CV.

N/A

3. Research (duties, dates): Summarize research activities in the table below. Provide key contributions, and annotate key grants and publications or use a [Statement of Key Contributions](#). Refer to it here and attach it to the CV.

Research Activity / Key Contributions	Dates
See Statement of Key Contributions	

4. Administrative Activities (duties, dates): Describe administrative activities in the table below. To document administrative activities more extensively use a supplemental statement, refer to it here and attach it to the CV.

Administrative Activity	Date
Education Committee Member (Health Sciences Research, Mayo Clinic)	2000 to 2002
Education Committee Chair (Health Sciences Research, Mayo Clinic)	2002 to 2007
Education Committee Member (Clinical Research Training Program, Mayo Clinic)	2001 to 2006
Executive Committee Member (Clinical Research Training Program, Mayo Clinic)	2001 to 2005
Master's Examination Committee Member (Clinical Research Training Program, Mayo Clinic)	2002 to 2015
Curriculum Committee Chair (Clinical Research Training Program, Mayo Clinic)	2002 to 2006
Data Safety and Monitoring Board Member (Mayo Clinic Cancer Center)	2003 to 2006
Clinical Studies Oversight Committee Member (Mayo Clinic Cancer Center)	2003 to 2006
Neuro-Oncology Executive Committee Member (Mayo Clinic Cancer Center)	2003 to 2010
Neuro-Oncology Protocol Planning Committee Member (Mayo Clinic Cancer Center)	2003 to 2007
Education Committee Member (Mayo Graduate School)	2004 to 2006
Executive Committee Member (Department of Health Sciences Research, Mayo Clinic)	2004 to 2008
Education Programs Curriculum Committee Member (Center for Translational Activities, Mayo Clinic)	2006 to 2008
Division Chair (Division of Biostatistics, Health Sciences Research, Mayo Clinic)	2006 to 2008
Peer Review Research Committee Member (Department of Surgery, Mayo Clinic)	2011 to 2015
Research Executive Committee Member (Department of Surgery, Mayo Clinic)	2011 to 2015

Research Committee Member (Department of Surgery, Mayo Clinic)	2011 to 2015
Data Safety and Monitoring Board Member (Department of Surgery, Mayo Clinic)	2012 to 2015
Division Chief for Healthcare Policy & Research	2015 to present
Healthcare Policy & Research Promotions Committee Member	2015 to present
Weill Cornell Medicine Data Safety and Monitoring Board (alternative) Co-Chair	2017 to present

H. RESEARCH SUPPORT

Summarize Past Research Support:

1. The Mayo Clinic Research Training Program funded by National Center for Research Resources (K30 RR 22296) from 06/1999 to 09/206 ; role: Associate Director
2. Risk Factors for Venous Thromboembolism in the Community funded by NHLBI (R01 HL 66216) from 04/2001 to 04/2005; role: Co-investigator
3. Angiotensin-II Blockade in Mitral Regurgitation funded by NHLBI (R01 HL 64928) from 04/2001 to 03/2005; role: Co-investigator
4. Core 1: Statistical and Administrative Core in: Gene Therapy for Vaso-occlusive disease funded by NHLBI (P01 HL 66958) from 09/2001 to 08/2008; role: Co-investigator
5. Core B: Study Design and Analysis Core in: Molecular Markers of Glioma Initiation & Progression funded by NCI (P01 CA 85799) from 06/2001 to 05/2006; role: Principal Investigator
6. GSK-3 and Associated Pathways in PNET funded by NINDS (R01 NS 40794) from 07/2002 to 11/2005; role: Collaborator
7. Mitochondria and surgical myopreservation in aging funded by NIA (R01 AG 21201) from 09/2002 to 08/2008; role: Consultant
8. Heart Failure in the Community funded by NHLBI ((R01 HL 72435) from 01/2003 to 06/2007; role: Co-investigator
9. Flavopiridol as a Potential Therapy in Multiple Myeloma funded by NCI (R01 CA 98118) funded from 07/2003 to 06/2008; role: Co-investigator
10. MAGE-A3/HPV 16 Peptide Vaccines for Head and Neck Cancer funded by the NIDCR (R01 DE 15324) from 04/2004 to 12/2004; role: Co-investigator
11. Xenograft Model for Studying Amplified EGFR in GBM funded by NCI (R01 NS 49720) from 08/2004 to 05/2006; role: Co-investigator
12. Brain Tumor SPORE - Core B – Biostatistics funded by NCI (P50CA 108961) from 09/2004 to 08/2014; role: Core Director
13. Global Differential Expression Profiling During Sudden Tumor Progression Using the Tumor Dedifferentiation Phenomenon as a Model funded by Mayo Clinic Foundation (CR20) from 04/2006 to 06/2010; role: Co-investigator
14. Measles Virotherapy for Glioblastoma Multiforme funded by NCI (R21 CA 123839) from 08/2006 to 07/2010; role: Co-investigator
15. Utility of Serum and Tissue Biomarkers for Predicting Response to Androgen Deprivation Therapy in the Population of Men with Rising PSA Following Definitive Treatment in: SPORE in Prostate Cancer funded by NCI (P50 CA 91956) from 09/2006 to 08/2013 ; role: Co-investigator
16. SPORE in Prostate Cancer—Biostatistics Core funded by NCI (P50 CA 91956) from 09/2006 to 08/2013; role: Core Director
17. Statistical Responsibilities for American College Of Surgical Oncology Group (ACOSOG) funded by NCI (U10 CA 76001) with subcontract to Mayo from 03/2006 to 11/2014; role: Principal Investigator
18. Epigenetic regulation of temozolomide responsiveness in glioblastoma funded by NCI (R01 CA 127716) from 01/2008 to 12/2012; role: Co-Investigator
19. Correlative Science and Imaging Analysis for Z1031 funded by Breast Cancer Research Foundation (WU-09-200) with subcontract to Mayo from 10/2008 to 09/2009; role: Principal Investigator
20. A phase III randomized Double Blind study of Adjuvant ST1571 (Gleevee) versus Placebo in patients following the Resection of primary gastrointestinal Stromal Tumor (GIST) funded by Novartis from 12/2008 to 06/2009; role: Principal Investigator
21. Mayo Comprehensive Cancer Center Grant funded by NCI (P30CA 15083) from 03/2009 to 07/2015; role: Statistician
22. Novel Biomarkers for Aromatase Inhibitor Therapy funded by NCI (R01 CA 95614) from 04/2009 to 12/2011; role: Principal Investigator

23. Optimizing Measles Virotherapy in the Treatment of Gliomas funded by NCI (R01CA 140620) from 07/2009 to 03/2011; role: Co-investigator
24. ACOSOG Community Clinical Oncology Program (CCOP) Research Base funded by NCI (U10CA 149950) from 06/2010 to 07/2014; role: Co-investigator
25. Treatment patterns of patients with newly diagnosed malignant primary brain tumors funded by Monteris Medical from 09/2010 to 08/2011; role: Principal Investigator
26. Statistical Responsibilities for American College Of Surgical Oncology Group (ACOSOG) in: Industry Supplement of Statistical Responsibilities for American College Of Surgical Oncology Group (ACOSOG) funded by Duke Clinical Research Institute from 12/2010 to 11/2011; role: Principal Investigator
27. N1037 P95HER2 expression in metastatic breast cancer patients treated with trastuzumab on N0337 and NCCTG 98-32-52 funded by BioTheragnostics/BioMerieux from 10/2011 to 3/2012; role: Co-investigator
28. Part 1 N9831F-NCCTG-ICSC Validation study of Quantitative Single Gene Assessment of HER2 mRNA by qRT-PCR and Development and Testing of New HER2 Multi-Gene Signature funded by Genomic Health, Inc. from 04/2012 to 05/2015; role: co-Principal Investigator
29. Therapeutic Strategy to Slow Progression of Calcific Aortic Valve Stenosis funded by National Center for Advancing Translational Sciences (UH2TR 000954) from 06/2013 to 07/2015; role: Co-investigator
30. Patient Centered: Risk Stratified Surveillance After Curative Research of Colorectal Cancer funded by a subcontract from a PCORI grant (CE-1304-6855) from 03/2014 to 07/2015; role: Principal Investigator
31. Post-Treatment Surveillance in Breast Cancer: Bringing CER to the Alliance funded by a subcontract from a PCORI grant (CE-1304-6543) from 03/2014 to 07/2015; role: Principal Investigator
32. Statistics and Data Center for the Alliance for Clinical Trials in Oncology funded by NCI (U10CA 180882) from 04/2014 to 07/2015; role: Co-investigator
33. Alliance NCORP Research Base funded by NCI (UG1CA 189823) from 08/2014 to 07/2015; role: Co-investigator
34. Improving How We Predict Toxicity for Older Women with Breast Cancer funded by Susan G. Komen Breast Cancer Foundation from 10/2014 to 09/2017; role: Principal Investigator (subsite)
35. Sarcoma Foundation from 11/2015 to 05/2017; role: Principal Investigator
36. Clinical and Translational Science Center (2UL1 TR000457) funded by NIH from 06/01/12 to 05/31/17; role: Co-Investigator

For Current extramural and intramural research funding, provide the following for each award:

1. Source, amount, and duration of support (dates)
2. Name of Principal Investigator
3. Individual's role in project, including percentage (%) effort

Current Research Support (duplicate table as needed):

Source	NCI (U01CA 157715) subcontract SPECS Grant
Amount	\$85,700 (subcontract amount of the larger grant)
Duration	07/2012 to 06/2018
Principal Investigator	Fred Hirsch
Your Role in Project	Co-investigator (PI of the subcontract to WCMC)
% Effort	5%

Source	NCI (U10CA 180882) subcontract Alliance
Amount	\$93,009
Duration	04/2014 to 02/2019
Principal Investigator	Dan Sargent
Your Role in Project	Co-investigator (PI of the subcontract to WCMC)
% Effort	20%

Source	SU2C
Amount	\$13,515
Duration	08/2017 – 06/2020
Principal Investigator	Lewis Cantley
Your Role in Project	Co- Investigator
% Effort	5%

Source	National Institutes of Health 1UL1TR002384-01
Amount	\$5,319,707
Duration	09/2017 to 06/2022
Principal Investigator	Julianne Imperato-Mcginley
Your Role in Project	Co-Investigator
% Effort	6%

Source	NCI (5U54CA 168512) SARC Sarcoma SPORE
Amount	\$97,045
Duration	09/2016 to 08/2018
Principal Investigator	Laurence Baker, Raphael Pollock, Denise Reinke
Your Role in Project	Principal Investigator (Subcontract)
% Effort	5%

Source	Prostate Cancer Foundation
Amount	\$1,000,000
Duration	7/2017 to 8/2018
Principal Investigator	Scott Tagawa
Your Role in Project	Co-Investigator
% Effort	5%

Source	Department of Defence (Subcontract with Duke University)
Amount	\$170,266
Duration	11/2017 to 10/2020
Principal Investigator	David Harpole
Your Role in Project	Principal Investigator (Subsite)
% Effort	10%

I. EXTRAMURAL PROFESSIONAL RESPONSIBILITIES

i.e. – Journal Reviewer, Editorial Boards, Study Sections, Invited Presentations

Activity / Responsibility	Dates
Reviewer The American Math Monthly	1991 to 1999
Gender and Ethnic Division Committee Member North Central Cancer Treatment Group	2002 to 2005
Neuro-Oncology Committee Member North Central Cancer Treatment Group	2002-2006
Reviewer The American Statistician	1994 to 1999
Editorial board member	1998 to 2003

Journal of Statistics Education	
Reviewer Mayo Clinic Proceedings	2001 to 2004
Reviewer Circulation	2003 to 2006
NCI Review Panel Member Consortium Therapeutic Studies of Primary Central Nervous System Malignancies in Adults	2003, 2008
Reviewer Bioinformatics	2004 to present
NCI Study Section ad hoc Member Scientific Review Group Subcommittee H-Clinical	2004, 2007, 2008
Reviewer Cancer Research	2004 to present
Editorial Board Neuro-Oncology	2004-2014
Reviewer American Journal of Gastroenterology	2005 to 2006
Review Panel Member Academic Public-Private Partnership Program (AP4)	2005
NCI-Avon Foundation Review Panel Member PFP Awards Program	2005 to 2006
NCI Review Panel Member Advanced Proteomic Platforms and Computation Sciences for the NCI Clinical Proteomic Technologies Initiative Review Panel	2006
Executive Committee Member American College of Surgeons Oncology Group	2006 to 2012
NCI Committee Member Breast Cancer Intergroup Committee	2007 to 2009
NCI Committee Member Breast Cancer Intergroup Correlative Sciences Committee	2008 to 2009
NCI Study Section Member Scientific Review Group Subcommittee H-Clinical	2009 to 2012
NCI Steering Committee Member Gastrointestinal Stromal Tumor Working Group	2009-2013
NCI Steering Committee Member Brain Malignancies	2009 to present
NCI Review Panel Member Novel Methodologies	2006
Data Monitoring Committee Member American College of Surgeons Oncology Group	2006 to 2011
Breast Cancer Committee Lead Statistician American College of Surgeons Oncology Group	2006 to 2011
Reviewer Biometrics	2006
NIAID Review Panel Member Cooperative Study Group for Autoimmune Disease Prevention	2006
Clinical Scientific Review Committee Member American College of Surgeons Oncology Group	2006 to 2011
Reviewer International Journal of Cancer	2006 to present
NICHHD Review Panel Member Obstetrical Pharmacology Research Network-Data Coordination and Analyses Center (OPRU-DCAC)	2007
Canada Cancer Society Review Panel Grant Application Review	2007
Editorial Board Journal of Clinical Oncology	2007 to 2010
NIAID Review Panel Member	2008

Proteomics Centers for Infectious Diseases and Biodefense	
NIDDK Review Panel Member Hepatitis B Clinical Research Network (U01)	2008
NIH Review Panel Member Data Management and Coordinating Center DMCC for the Rare Diseases Clinical Research Network (RDCRN)	2008
NIDDK Review Panel Member Multi-disciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network (U01)	2008
Data Monitoring Committee Member Astra-Zeneca Phase III Trial	2008-2012
Reviewer EURASIP Journal on Bioinformatics and Systems Biology	2008 to present
NCI Committee Member Clinical Trials Advisory Committee, Operational Efficiencies Working Group	2008 to 2009
NICHHD Review Panel Member Best Pharmaceuticals for Children Act Data Coordinating Center	2009
MN Partnership for Biotechnology and Medical Genomics Review Panel Member Scientific review of grant proposals	2009
NIDA Review Panel Member Data and Statistics Center for NIDA Clinical Trials Network	2009
Thoracic Cancer Committee Lead Statistician American College of Surgeons Oncology Group	2009 to 2011
Reviewer British Journal of Cancer	2009 to present
Reviewer Clinical Trials	2009 to present
Reviewer Plos1	2009 to present
NCI Review Panel Member Clinical Proteomic Technologies for Cancer Initiative: Proteome Characterization Centers	2010
NICHHD Review Panel Member Pediatric Trials Network	2010
Review Panel Member National Cancer Institute of Canada	2010
DOD CDMRP Review Panel Member Prostate Cancer Research Program	2010, 2011, 2012
Data Monitoring Committee Chair University of Minnesota Iron Study	2010 to 2014
Data Monitoring Committee Member Eli Lilly 14T-MC-JVBB Trial	2010 to 2014
Data Monitoring Committee Incyte RESPONSE Trial	2010 to 2014
Associate Editor Journal of Clinical Oncology	2010 to 2017
Deputy Editor Journal of Clinical Oncology	2017-present
Reviewer Nature	2010, 2013, 2017
NICHHD Review Panel Member Systematic Review of Neonatal Medicine	2011
NICHHD Review Panel Member Maintenance of Child Health and Development Studies Name and Address Files	2011
Dutch Cancer Society Review Panel Member Scientific Grant Review	2011, 2014, 2015
Reviewer Annals of Surgery	2011 to present
Operations Committee Member	2011 to 2015

Alliance Adult Cancer Cooperative Group	
Scientific Concept Peer Review Committee Member	2011 to 2014
Alliance Adult Cancer Cooperative Group	
Data Safety Monitoring Board Chair	2011 to present
Kanas University PAD in AA Trial	
NICHHD Review Panel Member	2012
Folic Acid Supplementation and Semen Quality Trial (FAAST)	
NIAID Review Panel Member	2012
Pre-Clinical Pharmacology and Toxicology Studies	
NCI Review Panel	2012
Pre-clinical Efficacy and Intermediate Endpoint	
NIDA Review Panel	2012, 2014
Data, Statistics, and Clinical Trial Support for NIDA	
Cancer in the Elderly Committee Lead Statistician	2012 to 2015
Alliance Adult Cancer Cooperative Group	
NICHHD Review Panel Member	2013
Multiple Study Data Coordinating Center for DESPR	
Mayo Clinic Review Panel Member	2013
Microbiome Program Clinic Trial Funding	
DOD CDMRP Review Panel Member	2013, 2015
Psychological Health/Traumatic Brain Injury Research Program	
NICHHD Review Panel Member	2013
Further Investigation into the Causes of Stillbirth Concept Clearance	
Publications Committee Member	2013 to 2016
Alliance Adult Cancer Cooperative Group	
Neuro-Oncology Committee Lead Statistician	2013 to present
Alliance Adult Cancer Cooperative Group	
FDA Medical Devices Advisory Committee Member	2013 to present
General and Plastic Surgery Devices	
Damon Runyon Foundation Review Panel Member	2013 to present
Clinical Investigator Award	
NCI Review Panel Member	2014, 2015
PLCO Secondary Studies Proposals	
NIAID Review Panel Member	2014
Inner City Asthma Consortium (ICAC3)	
DOD CDMRP Review Panel Member	2014
Vision Research Program	
Associate Editor	2014 to present
Neuro-Oncology	
Data Safety and Monitoring Board Committee Member	2014 to present
NIDDK	
NICHHD Review Panel Member	2015
P01 Pre-Natal Microbiome Grant Review	
NIAID Review Panel Member	2015
Centers for Medical Countermeasures against Radiation Consortium (U19)	
U.S. Army and the Army Medical Research and Materiel Command Review Panel	2015
Army Broad Agency Announcement (BAA)	
Cancer Research UK Review Panel Member	2015
Biomarker Project Award	
DOD CDMRP Review Panel Member	2015-2018
Statistical Associate Editor	2015 to present
American Journal of Respiratory and Critical Care Medicine	
NIAMS Technical Evaluation Panel Member	2016
Clinical Studies Management and Support	
NIAID Scientific Review Panel Member	2016
Asthma and Allergic Diseases Cooperative Research Centers	
NICHHD Technical Evaluation Panel Member	2016
Best Pharmaceutical for Children Act Data Coordinating Center	
NINDS Scientific Review Panel Member	2016

Parkinson's Disease Biomarkers Program	
Cancer Research United Kingdom Review Panel Member Program Project Submission	2016
United States Army Medical Research and Materiel Command (MRMC) Peer Review Panel Member	2016-2018
KNOD study section ad hoc reviewer	2018
Cancer Moonshot Initiative: Human Tumor Atlas Research Centers (U2C) review panel member	2018
Clinical Research Training Institute Summer Workshop Faculty Member American Society of Hematology	2016 -
Cancer LinQ Publications Committee Member	2016 -
STATS.org Statistical Advisory Board Member	2016 -

J. PROFESSIONAL MEMBERSHIPS

Include medical and scientific societies.

Member/Officer/Fellow/Role	Organization	Dates
Member	Operations Research Society of America	1990 to 1993
Officer	Operations Research Society of America	1992
Member	Mathematical Association of America	1991 to 1997
Officer	American Statistical Association	2000 to 2003; 2011 to 2013
Member	American Society of Clinical Oncology	2005 to present
Member	International Biometric Society, East North American Region	2006 to present
Officer	International Biometric Society, East North American Region	2008 to 2011
Member	Society of Clinical Trials	2008 to present

K. HONORS AND AWARDS

Name of award	Date awarded
Pi Mu Epsilon (Math honorary) - Macalester College	1980
Phi Beta Kappa - Macalester College	1982
Magna Cum Laude - Macalester College	1983
Academic All-American, Division III Volleyball - Macalester College	1983
Fredrick Hennie II Teaching Award - Massachusetts Institute of Technology	1987
Health Sciences Research Distinguished Teaching Award - Mayo Clinic	2004
Macalester College Distinguished Alumni in Science	2015

L. BIBLIOGRAPHY

1. Articles in professional peer-reviewed journals

1. **Ballman KV.** Greater emphasis on variation in an introductory statistics course. J Statistics Education. 1997; 5(2).
2. Singh M, Nuttall GA, **Ballman KV**, Mullany CJ, Berger PB, Holmes DR Jr, Bell MR. Effect of abciximab on the outcome of emergency coronary artery bypass grafting after failed percutaneous coronary intervention. Mayo Clin Proc. 2001 Aug; 76(8):784-8. PMID:11499816. DOI:10.1016/S0025-6196(11)63221-7.
3. McConnell JP, Branum EL, **Ballman KV**, Lagerstedt SA, Katzmann JA, Jaffe AS. Gender differences in C-reactive protein concentrations - Confirmation with two sensitive methods. Clinical Chemistry & Laboratory Medicine. 2002; 40(1):56-9. PMID:11916271.
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- elevation of creatine kinase but with elevation of cardiac troponin I levels. *Am J Cardiol.* 2002 Oct 15; 90(8):875-8. PMID:12372578.
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10. Takemoto Y, Tanabe K, Chandrasekaran KW, **Ballman KV**, Seward JB, Belohlavek M. Single-plane and biplane echocardiography: Use of targeted scan planes improves the estimates of left ventricular volume and shape for analysis of postinfarction remodeling. *J Am Soc Echocardiogr.* 2003 May; 16(5):448-56. PMID:12724654.
11. Barretto S, **Ballman KV**, Rooke TW, Kullo IJ. Early-onset peripheral arterial occlusive disease: clinical features and determinants of disease severity and location. *Vasc Med.* 2003 May; 8(2):95-100. PMID:14518611.
12. Gami AS, Wright RS, **Ballman KV**, Kopecky SL, Hayes SN. Hormone replacement therapy and risk of acute myocardial infarction in postmenopausal women with diabetes mellitus. *Am J Cardiol.* 2003 May 15; 91(10):1275-7. PMID:12745121.
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15. Michels VV, Olson TM, Miller FA, **Ballman KV**, Rosales AG, Driscoll DJ. Frequency of development of idiopathic dilated cardiomyopathy among relatives of patients with idiopathic dilated cardiomyopathy. *Am J Cardiol.* 2003 Jun 1; 91(11):1389-92. PMID:12767445.
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Exhibit 141

Gregory B. Diette, M.D.

Page 1

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

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IN RE JOHNSON & JOHNSON) MDL No.
TALCUM POWDER PRODUCTS) 16-2738 (FLW)(LHG)
MARKETING SALES PRACTICES,)
AND PRODUCTS LIABILITY)
LITIGATION)
)
THIS DOCUMENT RELATES TO)
ALL CASES)

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VIDEOTAPED DEPOSITION OF

GREGORY B. DIETTE, M.D.

TOWSON, MARYLAND

TUESDAY, APRIL 9, 2019

8:58 A.M.

Reported by: Leslie A. Todd

Gregory B. Diette, M.D.

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<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S 2 3 ON BEHALF OF THE PLAINTIFFS: 4 MICHELLE PARFITT, ESQUIRE 5 ADAM K. ROSEN, ESQUIRE 6 ASHCRAFT & GEREL, LLP 7 1825 K Street, N.W. 8 Suite 700 9 Washington, D.C. 20006 10 (202) 783-6400 11 12 CHRISTOPHER V. TISI, ESQUIRE 13 LEVIN PAPANTONIO THOMAS MITCHELL 14 RAFFERTY PROCTOR, P.A. 15 316 South Baylen Street 16 Pensacola, Florida 32502 17 (850) 435-7000 18 19 DENNIS M. GEIER, ESQUIRE 20 COHEN PLACITELLA ROTH, PC 21 127 Maple Avenue 22 Red Bank, New Jersey 07701 23 (732) 747-9003 24 25</p>	<p style="text-align: right;">Page 5</p> <p>1 APPEARANCES (Continued): 2 3 KATHERINE MCBETH, ESQUIRE 4 DRINKER BIDDLE & REATH, LLP 5 One Logan Square, Suite 2000 6 Philadelphia, Pennsylvania 19103-69896 7 (215) 988-2706 8 9 JESSICA D. MILLER, ESQUIRE 10 SKADDEN, ARPS, MEAGHER & FLOM, LLP 11 1440 New York Avenue, N.W. 12 Washington, D.C. 20005 13 (202) 371-7000 14 15 ON BEHALF OF THE PCPC: 16 THOMAS T. LOCKE, ESQUIRE 17 SEYFARTH SHAW LLP 18 975 F Street, N.W. 19 Washington, D.C. 20004-1454 20 (202) 463-2400 21 22 ALSO PRESENT: 23 DANIEL HOLMSTOCK, Videographer 24 25</p>

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<p>1 EXHIBITS (Continued)</p> <p>2 (Attached to transcript)</p> <p>3 DIETTE DEPOSITION EXHIBITS PAGE</p> <p>4 No. 28 Table 2.8 Epidemiologic studies of</p> <p>5 asbestos exposure and ovarian cancer</p> <p>6 (and, for comparison, lung cancer</p> <p>7 and mesothelioma) 396</p> <p>8 No. 29 Article entitled "Association between</p> <p>9 Body Powder Use and Ovarian Cancer:</p> <p>10 The African American Cancer</p> <p>11 Epidemiology Study (AACES)" 413</p> <p>12 No. 30 Article entitled "Perineal Talc Use</p> <p>13 and Ovarian Cancer, A Systematic</p> <p>14 Review and Meta-Analysis" 416</p> <p>15 No. 31 Ultrastructural Pathology article,</p> <p>16 "Correlative polarizing light and</p> <p>17 scanning electron microscopy for</p> <p>18 the assessment of talc in pelvic</p> <p>19 region lymph nodes" 427</p> <p>20 No. 32 Letter to Samuel Epstein from the</p> <p>21 Department of Health and Human</p> <p>22 Services, dated April 1, 2014 431</p> <p>23 No. 33 Facsimile dated September 30,</p> <p>24 2004 to Luzenac America from</p> <p>25 Richard Zazenski to Bill Ashton 437</p>	<p>1 PROCEEDINGS</p> <p>2 -----</p> <p>3 THE VIDEOGRAPHER: We are now on the</p> <p>4 record, and my name is Daniel Holmstock. I am the</p> <p>5 videographer for Golkow Litigation Services.</p> <p>6 Today's date is April 9th, 2019, and the time on</p> <p>7 the video screen is 8:58 a.m.</p> <p>8 This video deposition is being held at</p> <p>9 the Sheraton Baltimore North Hotel, at 903 Dulaney</p> <p>10 Valley Road in Towson, Maryland, in the matter of</p> <p>11 Johnson & Johnson Talcum Powder Products</p> <p>12 Marketing, Sales Practices and Products Liability</p> <p>13 Litigation, MDL No. 2738, and is pending before</p> <p>14 the United States District Court for the Eastern</p> <p>15 District of New Jersey.</p> <p>16 Our deponent today is Dr. Gregory</p> <p>17 Diette.</p> <p>18 Counsel for appearances will be noted on</p> <p>19 the stenographic record. And our court reporter</p> <p>20 today is Leslie A. Todd, who will now administer</p> <p>21 the oath.</p> <p>22 GREGORY B. DIETTE, M.D.,</p> <p>23 and having been first duly sworn,</p> <p>24 was examined and testified as follows:</p> <p>25 DIRECT EXAMINATION</p>

4 (Pages 10 to 13)

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<p style="text-align: right;">Page 14</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Good morning, Dr. Diette. How are you?</p> <p>3 A Good morning. Fine, thanks.</p> <p>4 Q Good. We will dispense with the usual</p> <p>5 comments with regard to a deposition. I</p> <p>6 understand you've had --</p> <p>7 THE VIDEOGRAPHER: Microphone.</p> <p>8 BY MS. PARFITT:</p> <p>9 Q All right. Now we're back on the mic.</p> <p>10 Dr. Diette, we'll dispense with the</p> <p>11 usual comments with regard to what a deposition is</p> <p>12 about. I understand you've probably had your</p> <p>13 deposition taken more than a hundred times. Is</p> <p>14 that fair?</p> <p>15 A I don't know if it's a hundred, but --</p> <p>16 but plenty enough that I think that I -- I</p> <p>17 understand the process.</p> <p>18 Q All right. The only one that I will ask</p> <p>19 you to pay some attention to is the fact that if</p> <p>20 you don't understand my question, please let me</p> <p>21 know. Otherwise, I'm going to assume you</p> <p>22 understand every question that I ask, and the</p> <p>23 answers that you're giving are truthful and</p> <p>24 accurate. Fair enough?</p> <p>25 A It is.</p>	<p style="text-align: right;">Page 16</p> <p>1 jury.</p> <p>2 A Sure. It's Gregory --</p> <p>3 MS. BROWN: Objection. There's no jury</p> <p>4 here.</p> <p>5 MS. PARFITT: There may be.</p> <p>6 MS. BROWN: Go ahead, Dr. Diette.</p> <p>7 THE WITNESS: My parents gave it to me,</p> <p>8 for what it's worth, but it's Gregory Bruce</p> <p>9 Diette.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Okay. Very good.</p> <p>12 Dr. Diette, what I'd like to do is mark</p> <p>13 as Exhibit 1 a notice of the deposition.</p> <p>14 (Diette Exhibit No. 1 was marked</p> <p>15 for identification.)</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Dr. Diette, if I may, Exhibit 1 is the</p> <p>18 notice of deposition. Have you seen that document</p> <p>19 before?</p> <p>20 A Yeah, I've certainly seen -- seen</p> <p>21 something just like this.</p> <p>22 Q All right. Do you see at the back of</p> <p>23 the deposition, there is a notice that -- there is</p> <p>24 a request for you to bring certain information to</p> <p>25 your deposition? Do you see that?</p>
<p style="text-align: right;">Page 15</p> <p>1 Q All right. Now, you're sitting here</p> <p>2 today in Towson, Maryland, in a Sheraton Hotel; is</p> <p>3 that correct?</p> <p>4 A That is.</p> <p>5 Q All right. You are normally, I believe,</p> <p>6 over at Johns Hopkins University Medical Center,</p> <p>7 correct?</p> <p>8 A That's right.</p> <p>9 Q All right. Is your department aware of</p> <p>10 the fact that you're sitting over here having a</p> <p>11 deposition taken?</p> <p>12 A I don't know if anybody knows about this</p> <p>13 today, but they wouldn't be surprised, I mean, to</p> <p>14 hear it if I told them.</p> <p>15 Q All right. They know that you</p> <p>16 frequently give depositions so they would not be</p> <p>17 surprised; is that correct?</p> <p>18 MS. BROWN: Objection to form.</p> <p>19 THE WITNESS: They -- I don't know about</p> <p>20 frequently, but they know that -- that I do give</p> <p>21 depositions.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q All right. Very good.</p> <p>24 Would you please introduce your formal</p> <p>25 God-given name for the ladies and gentlemen of the</p>	<p style="text-align: right;">Page 17</p> <p>1 A Yes.</p> <p>2 Q All right. Have you had a chance to</p> <p>3 review that?</p> <p>4 A I have.</p> <p>5 Q All right. How recently?</p> <p>6 A Last week sometime.</p> <p>7 Q All right. Was it provided to you by</p> <p>8 counsel?</p> <p>9 A I think that's the only way I could get</p> <p>10 it.</p> <p>11 Q Okay. Very good.</p> <p>12 Now, yesterday, perhaps early in the</p> <p>13 morning, I was also provided a copy of the</p> <p>14 Defendants' Response to the Plaintiffs' Document</p> <p>15 Requests Contained in the Notice of Oral and</p> <p>16 Videotaped Deposition.</p> <p>17 Let me show you what we will have marked</p> <p>18 as Exhibit No. 2.</p> <p>19 (Diette Exhibit No. 2 was marked</p> <p>20 for identification.)</p> <p>21 BY MS. PARFITT:</p> <p>22 Q Dr. Diette, let me present you with a</p> <p>23 copy of Exhibit No. 2.</p> <p>24 All right. Dr. Diette, my understanding</p> <p>25 is that this document, Exhibit No. 2, represents</p>

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<p>1 your responses to the requests that were</p> <p>2 propounded upon you to -- for documents and other</p> <p>3 materials prior to your deposition, correct?</p> <p>4 MS. BROWN: Objection to the form. It</p> <p>5 represents the lawyer's objections to the document</p> <p>6 requests you served.</p> <p>7 MS. PARFITT: Fair.</p> <p>8 THE WITNESS: I -- I think Ms. Brown's</p> <p>9 got it right.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q All right. Did you -- well, let's have</p> <p>12 marked the attachment to the response to</p> <p>13 plaintiffs' document, which was prepared by your</p> <p>14 lawyers. And let's separately mark as Exhibit</p> <p>15 No. 3 the attachments, if you will.</p> <p>16 A Should I pull this apart or -- or you</p> <p>17 want to do that?</p> <p>18 Q And for purposes of the record,</p> <p>19 Exhibit 2 will represent the entire document, the</p> <p>20 response to plaintiffs' request, and No. 3 will</p> <p>21 represent just the attachments to the request,</p> <p>22 which would be material that you, Dr. Diette, were</p> <p>23 to provide.</p> <p>24 (Diette Exhibit No. 3 was marked</p> <p>25 for identification.)</p>	<p>1 much.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q All right. Dr. Diette, number -- or</p> <p>4 Exhibit No. 3, the first document, Supplemental</p> <p>5 Materials Reviewed and Considered, did you prepare</p> <p>6 this Supplemental Materials Reviewed and</p> <p>7 Considered?</p> <p>8 A I contributed to it, but I didn't do the</p> <p>9 typing.</p> <p>10 Q Okay. What does that mean when you say</p> <p>11 you contributed to it?</p> <p>12 A I helped to clarify what other --</p> <p>13 because this -- this looks like it's all</p> <p>14 reports -- I just want to make sure what's here --</p> <p>15 reports, a couple of papers probably, and I -- I</p> <p>16 helped to verify that these were also things that</p> <p>17 I had -- had received and had a chance to look at.</p> <p>18 Q All right. So would it be fair to say</p> <p>19 that the 23 items listed on this were materials</p> <p>20 that somebody typed on a list and asked that you</p> <p>21 review it; is that correct?</p> <p>22 MS. BROWN: Objection to the form.</p> <p>23 Misstates his testimony.</p> <p>24 THE WITNESS: So I think, just in terms</p> <p>25 of the sequence, I mean I've gotten materials in</p>
Page 19	Page 21
<p>1 BY MS. PARFITT:</p> <p>2 Q And we'll briefly just review what's</p> <p>3 here, so we can move on to other areas.</p> <p>4 The first page of that document</p> <p>5 indicates supplemental materials reviewed and</p> <p>6 considered.</p> <p>7 MS. BROWN: Counsel, can we go off the</p> <p>8 record for a second?</p> <p>9 MS. PARFITT: Yes.</p> <p>10 THE VIDEOGRAPHER: The time is 9:03.</p> <p>11 We're going off the record.</p> <p>12 (Pause in the proceedings.)</p> <p>13 THE VIDEOGRAPHER: The time is 9:04 a.m.</p> <p>14 We're back on the record.</p> <p>15 MS. BROWN: Good morning. This is Ali</p> <p>16 Brown for J&J. We're back on the record, having</p> <p>17 taken a short break to put the cameras on both the</p> <p>18 questioner and myself, and we'll proceed, of</p> <p>19 course, with the camera on Dr. Diette. Thank you.</p> <p>20 MS. PARFITT: Thank you. And I should</p> <p>21 have asked, there's no one on the phone, is there,</p> <p>22 today?</p> <p>23 THE VIDEOGRAPHER: There is no phone</p> <p>24 present here today.</p> <p>25 MS. PARFITT: Perfect. Thank you very</p>	<p>1 this matter over a period of time, right. So they</p> <p>2 come in dribs and drabs. And a lot of this looks</p> <p>3 like some of the more recent things that came, you</p> <p>4 know, because you guys have been doing</p> <p>5 depositions, and some of the reports came in later</p> <p>6 and so forth. So it's really -- that's how I got</p> <p>7 the materials, and then this is just to make sure</p> <p>8 that I had a complete list of everything that I've</p> <p>9 gotten.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q All right. And the reason I asked is</p> <p>12 because you submitted your report on</p> <p>13 February 25th, 2019. So may I assume that</p> <p>14 everything on the list, Exhibit No. 3, the first</p> <p>15 page, supplemental, represents documents you</p> <p>16 received after February 25th, 2019, correct?</p> <p>17 MS. BROWN: Objection to the form.</p> <p>18 THE WITNESS: I wouldn't assume that. I</p> <p>19 mean, so certainly some things here, right. So</p> <p>20 the expert reports that are dated 2/25, I didn't</p> <p>21 have, you know, even on the day that I submitted</p> <p>22 mine, so those came after. Something like the</p> <p>23 Barnard study, I may well have had that. I mean,</p> <p>24 my -- my goal here was to -- just to make sure</p> <p>25 that we hadn't left anything off.</p>

6 (Pages 18 to 21)

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<p style="text-align: right;">Page 22</p> <p>1 BY MS. PARFITT:</p> <p>2 Q All right. Is it fair to say that the</p> <p>3 items that are listed on Exhibit No. 2 -- 3 were</p> <p>4 not items that you considered for purposes of the</p> <p>5 opinions you've expressed in your report of</p> <p>6 February 25th, 2019?</p> <p>7 MS. BROWN: Objection to the form.</p> <p>8 THE WITNESS: So I -- it's very possible</p> <p>9 that the Barnard study I did consider. Trabert, I</p> <p>10 can't remember. But definitely, right, the expert</p> <p>11 reports that are dated on 2/25, I couldn't have</p> <p>12 considered. And anything that's a deposition</p> <p>13 transcript that happened after 2/25, obviously I</p> <p>14 couldn't have considered that either.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q All right. Very good.</p> <p>17 The information thereafter, I believe we</p> <p>18 have -- one, two, three -- four invoices. They</p> <p>19 begin with the date of 12/14/2018, and end with a</p> <p>20 date of 3/15/19.</p> <p>21 Are there any other invoices that you</p> <p>22 would like to share with me today?</p> <p>23 A I don't have any others that I'm aware</p> <p>24 of.</p> <p>25 Q Are you preparing any invoices for your</p>	<p style="text-align: right;">Page 24</p> <p>1 Q All right. Let me get this straight.</p> <p>2 Your hourly rate is 485.</p> <p>3 A Well, sort of. I'll describe it if</p> <p>4 you'd like here.</p> <p>5 Q Well, I -- you can understand my</p> <p>6 confusion. If your hourly rate is 485, I want to</p> <p>7 know you're -- why I'm getting --</p> <p>8 A You don't need to be confused for very</p> <p>9 long, though.</p> <p>10 MS. BROWN: Hold on. Hold on.</p> <p>11 Counsel, you've got to let him answer</p> <p>12 the question.</p> <p>13 MS. PARFITT: Sure.</p> <p>14 MS. BROWN: He is endeavoring to set</p> <p>15 that straight.</p> <p>16 MS. PARFITT: Please.</p> <p>17 MS. BROWN: So go ahead.</p> <p>18 THE WITNESS: I think it's pretty easy.</p> <p>19 I charge \$400 an hour, and Medical Science</p> <p>20 Affiliates prepares this invoice, and part of</p> <p>21 their business model is to add an hourly rate</p> <p>22 to -- to my rate.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Okay. And I want to talk a little bit</p> <p>25 about that in a moment, but that's exactly one of</p>
<p style="text-align: right;">Page 23</p> <p>1 time post the very last invoice which is dated</p> <p>2 3/15/2019?</p> <p>3 A I will be.</p> <p>4 Q All right. How many hours have you</p> <p>5 spent since your submitting the invoice of</p> <p>6 3/15/2019?</p> <p>7 A Let's see, three -- I would estimate</p> <p>8 about -- about 20 hours or maybe 25 hours, give or</p> <p>9 take.</p> <p>10 Q All right. And what is your hourly</p> <p>11 rate?</p> <p>12 A So to clarify, so when on here it says</p> <p>13 it's 485, my -- my rate itself is actually \$400 an</p> <p>14 hour, and that's the amount that was charged.</p> <p>15 Q Okay. Now, is the amount that was</p> <p>16 charged, 400, because you worked with someone else</p> <p>17 who assists you with preparing the materials?</p> <p>18 A It's not --</p> <p>19 MS. BROWN: Objection to the form of the</p> <p>20 question.</p> <p>21 THE WITNESS: Sorry.</p> <p>22 MS. BROWN: Go ahead. You can answer.</p> <p>23 THE WITNESS: No, it's because that's</p> <p>24 how much I've asked to be paid is \$400 per hour.</p> <p>25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 25</p> <p>1 the issues I need some clarification on. But</p> <p>2 let's finish up the bills.</p> <p>3 A Mm-hmm.</p> <p>4 Q We have a bill for 12/14/2018 for</p> <p>5 \$17,103.75. Correct?</p> <p>6 A Correct.</p> <p>7 Q And we have a bill for 1/15/2018 for</p> <p>8 \$5,068.02, correct?</p> <p>9 A That's correct.</p> <p>10 Q We have a bill for 2/12/2019 for</p> <p>11 \$35,375. Is that correct?</p> <p>12 A It is.</p> <p>13 Q And we have a bill for \$20,973.75; is</p> <p>14 that correct?</p> <p>15 A It is.</p> <p>16 Q And then we have an additional 20, maybe</p> <p>17 25 hours that you will charge at the rate of \$400,</p> <p>18 although Medical Science Affiliates gets \$85 of</p> <p>19 that, correct?</p> <p>20 A That's correct, although I think -- I</p> <p>21 don't know if you're following -- well, that's</p> <p>22 correct. Go ahead.</p> <p>23 Q Okay. And we'll explore that in a</p> <p>24 minute.</p> <p>25 A Okay.</p>

7 (Pages 22 to 25)

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<p style="text-align: right;">Page 26</p> <p>1 Q Now, attached to that is -- it has an 2 exhibit on it, Plaintiffs' Exhibit No. 7, and it 3 appears to be several pages of notes. 4 Do you see that? 5 A I do. 6 Q All right. What are these notes? 7 A Well, these -- I haven't looked to see 8 for sure what's -- 9 MS. BROWN: And, Counsel, just to make 10 sure the record is clear, this was produced in 11 response per your request for his notes that were 12 marked at the Ingham deposition. So this exhibit 13 number is the marking from the Ingham deposition, 14 and these were the notes that he produced there 15 that I'm frankly sure you have access to, but in 16 the effort of cooperation, we reproduced them here 17 per your request. 18 BY MS. PARFITT: 19 Q So, Doctor -- 20 A It's -- oh, go ahead. I'm sorry. 21 Q Go ahead. You were going to tell me 22 what they are. 23 A Yeah, and I didn't know if that was 24 the -- the sufficient answer, because that's 25 literally, I guess, what they are right there.</p>	<p style="text-align: right;">Page 28</p> <p>1 that I just made as I was reading through 2 different articles. 3 Q Okay. Would -- 4 A No, I'm sorry. 5 Q Are you finished? 6 A No, that's just what I was going to say, 7 so these are -- it just represents just notes that 8 I was making at certain times when I was looking 9 at some of the articles. 10 Q Okay. When did you first start looking 11 at any of the articles? 12 A Sometime in -- by -- if we're talking 13 about the articles, meaning articles pertaining to 14 ovarian cancer and talcum powder, is it? 15 Q Well, it's a good question, because you 16 just said when you started looking at any of the 17 articles, are you talk- -- do these represent any 18 articles or do these represent articles of ovarian 19 cancer and talcum powder? 20 A Yeah, yeah. 21 MS. BROWN: And hold on, I think the 22 record is going to be unclear. When you say 23 "these," are you referring to what has been marked 24 as Plaintiffs' Exhibit 7 in response to your -- 25 MS. PARFITT: Correct.</p>
<p style="text-align: right;">Page 27</p> <p>1 These are -- they're an exhibit. But did you mean 2 something else, like -- 3 Q Well, now that I've had clarification by 4 your attorney, that does help a bit, but I do have 5 a couple of questions. 6 MS. MILLER: For the record, she's not 7 his attorney. She's J&J's attorney. 8 MS. PARFITT: We're going to have one 9 examiner today. So you and Ali decide who that's 10 going to be. 11 MS. BROWN: Okay. Counsel, let's keep 12 going with the questions for Dr. Diette so we 13 don't waste the doctor's time. 14 MS. PARFITT: Believe me, I don't want 15 to waste my time. So let's -- okay. I realize 16 every now and again it happens. 17 BY MS. PARFITT: 18 Q So, Dr. Diette, these are notes that you 19 prepared back at the time of the Ingham 20 deposition, correct? 21 A So not literally. Right, there are -- I 22 was asked, and I don't remember exactly what -- 23 what was on the notice, but I was asked to bring 24 any notes that I had made. So they're not 25 necessarily for the Ingham matter. They're notes</p>	<p style="text-align: right;">Page 29</p> <p>1 MS. BROWN: -- notice of deposition? 2 Okay. 3 THE WITNESS: So this would have been 4 sometime in 2017 that -- that I started. I don't 5 know if these notes were made in 2017, but I 6 just mean that that's the answer to when I started 7 to look at those article -- articles. 8 BY MS. PARFITT: 9 Q And we'll get to that timeline in a 10 moment. 11 Are there any additional notes that you 12 have prepared post Plaintiffs' Exhibit No. 7, 13 which I understand you presented at the Ingham 14 deposition? 15 A I don't think so. I'll give you an 16 example of something that I don't know whether you 17 consider it a note or not. 18 Q Okay. 19 A Like as I was preparing my report, I 20 would put like a -- like a little sticker on a 21 paper where I wanted to pull a quote into the -- 22 into the paper, and then I would tear that off and 23 throw it away because it wasn't, you know, useful 24 anymore. But nothing else that kind of -- that 25 looks like this.</p>

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<p style="text-align: right;">Page 30</p> <p>1 Q All right. So you would put a sticker</p> <p>2 on a paper like when I wanted to put a quote in,</p> <p>3 and then I tore it off.</p> <p>4 Are these medical records that -- or</p> <p>5 excuse me, medical articles that you were</p> <p>6 reviewing?</p> <p>7 A These are scientific articles, yeah, the</p> <p>8 ones that informed my report.</p> <p>9 Q All right. So do you have a stack of</p> <p>10 scientific and medical articles that informed your</p> <p>11 report at your office, at your home?</p> <p>12 A I've got -- I've got little piles of</p> <p>13 stuff everywhere you can look.</p> <p>14 Q Okay. Do any of them have markings on</p> <p>15 them or any stickies?</p> <p>16 A I don't think there's any stickies</p> <p>17 anymore. If they have markings, there could be</p> <p>18 some that have yellow highlights.</p> <p>19 Q All right.</p> <p>20 A But I don't think any that have like</p> <p>21 writing on them per se.</p> <p>22 Q Okay. But there might be yellow</p> <p>23 highlights on them, correct?</p> <p>24 A There sure could be, yeah. Not on all</p> <p>25 of them, but could be on some.</p>	<p style="text-align: right;">Page 32</p> <p>1 objections to those document requests, and</p> <p>2 Dr. Diette's testimony will be consistent with</p> <p>3 that.</p> <p>4 MS. PARFITT: My question -- are you</p> <p>5 objecting to providing me with a copy of</p> <p>6 Dr. Diette's agreement with Medical Science</p> <p>7 Affiliates?</p> <p>8 MS. BROWN: Well, we haven't even</p> <p>9 established that there is such a thing. I</p> <p>10 understand you to be getting into questions</p> <p>11 regarding Medical Sciences.</p> <p>12 MS. PARFITT: I will, yeah.</p> <p>13 MS. BROWN: I understand you've asked a</p> <p>14 number of document requests regarding Medical</p> <p>15 Sciences, and I just want to make sure that the</p> <p>16 record is clear that we have endeavored to respond</p> <p>17 to those and object accordingly.</p> <p>18 MS. PARFITT: Okay. And we're going to</p> <p>19 try and reduce the number of narrative objections</p> <p>20 if we can so we can get through this --</p> <p>21 THE WITNESS: I remember your question</p> <p>22 if you want me to answer it.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q I do.</p> <p>25 I wanted to know in response to request</p>
<p style="text-align: right;">Page 31</p> <p>1 Q All right.</p> <p>2 MS. PARFITT: I'll address this with</p> <p>3 counsel later, but I would request copies of all</p> <p>4 those highlighted articles that you may have</p> <p>5 somewhere. But we can talk about that --</p> <p>6 MS. BROWN: We can talk about that off</p> <p>7 the record.</p> <p>8 THE WITNESS: Okay.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q All right. So other than notations on</p> <p>11 some medical and scientific articles, there would</p> <p>12 be no additional notes like that which forms part</p> <p>13 of the part of Plaintiffs' Exhibit 7, correct?</p> <p>14 A Correct.</p> <p>15 Q All right. In the request to appear</p> <p>16 here at your deposition, there was an inquiry with</p> <p>17 regard to, I believe you called it, Medical</p> <p>18 Science Affiliates.</p> <p>19 A Correct.</p> <p>20 Q All right. Do you have a retainer</p> <p>21 agreement with Medical Science Affiliates?</p> <p>22 MS. BROWN: And I'm just going to</p> <p>23 interject here, Counsel. To the extent you've</p> <p>24 made a request for any documentation regarding</p> <p>25 Medical Science Affiliates, you have our</p>	<p style="text-align: right;">Page 33</p> <p>1 number 14, whether or not you have any contracts,</p> <p>2 agreements, writings conveying mutual</p> <p>3 understandings between you and Medical Science</p> <p>4 Affiliates or any entity of or related to Medical</p> <p>5 Science Affiliates for the past ten years?</p> <p>6 MS. BROWN: And, Counsel, I'm going to</p> <p>7 object to the extent that any of those requests or</p> <p>8 documentation involve work product that we have</p> <p>9 asserted privilege over, he will not be answering</p> <p>10 that question under the work-product privilege.</p> <p>11 MS. PARFITT: Okay, Counsel, you can</p> <p>12 assert work product. Got it. Is that what you're</p> <p>13 asserting right now?</p> <p>14 MS. BROWN: Yes. He's not going to</p> <p>15 answer that question. We're asserting work</p> <p>16 product.</p> <p>17 MS. PARFITT: So he is not going to</p> <p>18 answer my question with regard to any agreement or</p> <p>19 writing or contracts that he has with Medical</p> <p>20 Science Affiliates under the guidance of counsel</p> <p>21 that is objecting and refusing to have you answer</p> <p>22 that question. Is that correct -- record correct?</p> <p>23 MS. BROWN: That's correct, Counsel.</p> <p>24 MS. PARFITT: Okay.</p> <p>25 BY MS. PARFITT:</p>

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<p>1 Q And we're going to talk about Medical 2 Science in just -- just a moment. 3 Anything else other than the documents 4 that I have in front of you, Exhibit 7, the 5 invoice and your supplemental reliance, that you 6 have brought to your deposition today? 7 A So I didn't bring this today. 8 Q Okay. Fair enough. 9 A I mean I -- I didn't bring anything -- I 10 mean I didn't bring any materials to the 11 deposition. 12 Q Okay. 13 All right. Dr. Diette, what is your 14 profession? 15 A Well, I'm a physician, epidemiologist, 16 researcher. 17 Q Okay. You're actually a professor of 18 medicine at the Department of Pulmonary and 19 Critical Care, is that correct, at Johns Hopkins? 20 A Literally it's the Department of 21 Internal Medicine, and it's the Division of 22 Pulmonary, Critical Care, and Sleep Medicine. 23 Q Okay. Dr. Diette, do you agree that 24 ovarian cancer ranks as the fifth cause of 25 neoplastic death among women?</p>	<p>1 THE WITNESS: I've seen -- I've seen it 2 ranked highly. I don't remember if it was fifth, 3 but I've seen it ranked highly. 4 BY MS. PARFITT: 5 Q All right. Are you aware of the fact 6 that ovarian cancer accounts for more deaths than 7 any other cancer in the female reproductive 8 system? 9 A Ovarian cancer. Is that -- is that a 10 statement from a -- like a document or something? 11 Q It's a question. 12 A It's a question that -- 13 Q Do you know whether or not ovarian 14 cancer accounts for more deaths than any other 15 cancer of the female reproductive system? 16 A I know it's a highly ranked one. I 17 wouldn't be able to say whether it's more than all 18 others. 19 Q All right. Do you know whether 20 approximately 22,000 new cases of ovarian cancer 21 identified each year and 14,000 women 22 approximately will die in the United States alone 23 from ovarian cancer? 24 MS. BROWN: Objection to the form. 25 THE WITNESS: I haven't memorized</p>
Page 35	Page 37
<p>1 A I've seen -- I've seen it listed on -- 2 you know, on lists of causes of death. I don't 3 know what you mean by "agree with," but I mean -- 4 Q Do you have a difference of opinion as 5 to whether or not ovarian cancer ranks fifth with 6 regard to causes of neoplastic death among women? 7 MS. BROWN: Objection. Asked and 8 answered. 9 THE WITNESS: It doesn't seem to be 10 something that there's an opinion on. That's what 11 I mean. I mean it's like an objective fact. I 12 mean if there's a list that's put out by, you 13 know, government stats, and it's number 5 on that 14 list, that's -- that's an objective fact. 15 BY MS. PARFITT: 16 Q Do you object to that? 17 MS. BROWN: Let him answer, Counsel. 18 MS. PARFITT: I have. Thank you. 19 Are you objecting as -- 20 BY MS. PARFITT: 21 Q Let me ask you this, Doctor. 22 A Okay. 23 Q Have you seen that in any published 24 scientific literature? 25 MS. BROWN: Objection to the form.</p>	<p>1 anything with exact numbers like that. I mean I'm 2 not saying it's far off from the truth, and if you 3 have, you know, some document that supports that, 4 I'd be glad to look at it and see if it looks 5 right, but -- but I haven't memorized the exact 6 number. 7 BY MS. PARFITT: 8 Q All right. And you know, Dr. Diette, 9 this won't be a memory test, but I do understand 10 that you have spent almost \$100,000 in this case 11 alone reviewing medical and scientific articles, 12 so all I'm simply asking is that you provide me 13 with your best answers. Fair? 14 MS. BROWN: I object to the -- 15 MS. PARFITT: That's all, Counsel. 16 That's all -- 17 MS. BROWN: -- speech by counsel. He's 18 here to answer your questions. 19 MS. PARFITT: Counsel -- 20 MS. BROWN: That is a highly 21 objectionable statement, Counsel, and you know it. 22 If you have a question to ask him, he is here to 23 answer it. We're not going to be here to have you 24 give speeches on the record about the fees that he 25 has charged for the work that he has done.</p>

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<p style="text-align: right;">Page 38</p> <p>1 MS. PARFITT: Ms. Brown, your objection, 2 according to the CMO in the MDL case, perhaps 3 you're doing other state depositions, is that you 4 say, "Objection. Form." 5 And I'll try and do my best, if you'd do 6 the same. And I'm not admonishing you, and I hope 7 you're not admonishing me. That's not how I roll. 8 MS. BROWN: Well, the record is going to 9 be very clear -- 10 MS. PARFITT: It will be. 11 MS. BROWN: -- about the statement that 12 you just made about the other work that I'm doing. 13 MS. PARFITT: I said -- 14 MS. BROWN: I am well aware of the 15 CMO -- 16 MS. PARFITT: Perfect. Okay. 17 Counsel -- 18 MS. BROWN: -- and the deposition 19 protocol in this case. 20 MS. PARFITT: -- that's fine. 21 MS. BROWN: And I -- 22 MS. PARFITT: Counsel -- 23 MS. BROWN: -- expect that you will 24 abide by it -- 25 MS. PARFITT: -- let me ask questions.</p>	<p style="text-align: right;">Page 40</p> <p>1 thinking about your question before, I just wanted 2 to clarify that I -- because when you said that I 3 billed \$100,000, I think what you might be doing 4 is adding up all of those MSA invoices, which that 5 doesn't all go to me. I mean there's a way to 6 figure out how much that I've billed, but -- but 7 you wouldn't be correct if you're saying that 8 those four invoices represent the amount that I've 9 charged. 10 Q Okay. And we'll talk about that, but I 11 appreciate the clarification. 12 So, the other question is, do you have 13 an understanding that most ovarian cancer cases 14 are detected and diagnosed at a late stage and 15 there are limited prospects for cure? 16 MS. BROWN: Same objection. 17 THE WITNESS: I have that general 18 understanding. 19 BY MS. PARFITT: 20 Q Okay. Do you have any knowledge as to 21 what the mortality and morbidity of ovarian cancer 22 is? 23 A Well, the morbidity is not a number, 24 right. I mean you're talking about what are the 25 consequences?</p>
<p style="text-align: right;">Page 39</p> <p>1 MS. BROWN: -- and not interrupt me. 2 Thank you. 3 MS. PARFITT: I am not going to, but I 4 would ask the same courtesy. And, listen, we have 5 a long day to go, and it will be longer -- 6 MS. BROWN: Just ask the doctor a 7 question and move on. 8 MS. PARFITT: -- if we go back and 9 forth. "Objection, form" is the appropriate way, 10 or we will have to call the judge. 11 MS. BROWN: Happy to do it. 12 MS. PARFITT: Very good. So will I. 13 BY MS. PARFITT: 14 Q All right. Dr. Diette, do you have an 15 understanding from your review of the scientific 16 and medical literature that ovarian cancer cases 17 are detected and diagnosed at a late stage and 18 there are limited prospects for cure? 19 MS. BROWN: Objection to the form of the 20 question. 21 THE WITNESS: I didn't listen to what 22 you said because -- 23 BY MS. PARFITT: 24 Q Sure. 25 A But just for the reason that I'm still</p>	<p style="text-align: right;">Page 41</p> <p>1 Q You're right. 2 A And then the mortality would be 3 something that's an objective fact that there's a 4 percentage of people with the disease that die. 5 Q Right. 6 A I don't know the number. I didn't 7 memorize that. If it's important, we can look it 8 up, but it's a high -- it's a high proportion that 9 die from it. 10 Q Fair. Do you know what the latency is 11 for ovarian cancer? 12 A Between what and what? 13 Q The latency period between -- let's take 14 some examples -- asbestos and ovarian cancer. 15 MS. BROWN: Objection to the form of the 16 question. 17 You can answer if you understand. 18 THE WITNESS: So the -- that's a tricky 19 issue, I think in a way, because I'm not sure that 20 it's been fully established that asbestos causes 21 ovarian cancer. I mean I'm aware of what the IARC 22 has put out on it, but I'm not sure that that's a 23 fact. But I don't recall seeing in there where 24 the latency, if it was even true, whether that 25 was -- whether that was established.</p>

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<p>1 BY MS. PARFITT:</p> <p>2 Q All right. Have you in the course of --</p> <p>3 strike that.</p> <p>4 All right. From a review of the</p> <p>5 materials you reviewed attached to your expert</p> <p>6 report, Doctor, I see that you reviewed the Purdie</p> <p>7 case --</p> <p>8 MS. BROWN: Counsel -- Counsel, is there</p> <p>9 a page you want to point him to so we can follow</p> <p>10 along?</p> <p>11 MS. PARFITT: I'm still asking the</p> <p>12 question, Counsel.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Dr. Diette, attached to your report is a</p> <p>15 materials reviewed. And on page 7, it lists that</p> <p>16 you have read the Purdie case, which is a 1995</p> <p>17 case study -- excuse me, not case study, but a</p> <p>18 scientific article.</p> <p>19 MS. BROWN: Objection to the form.</p> <p>20 Take your time to get to that page,</p> <p>21 Doctor.</p> <p>22 THE WITNESS: It's 7 in my report?</p> <p>23 BY MS. PARFITT:</p> <p>24 Q It is on page 7 of your report.</p> <p>25 MS. BROWN: And, Counsel, I think we</p>	<p>1 Q Okay. All right. And we're going to</p> <p>2 talk about that in conjunction with -- just hold</p> <p>3 tight. I'm going to set that aside, and let me</p> <p>4 ask you this --</p> <p>5 A Can I ask just real quick?</p> <p>6 Q Sure.</p> <p>7 A There's like a cold breeze blowing down</p> <p>8 here, and I know we will regret making it warmer</p> <p>9 in here at some point.</p> <p>10 Q Sure.</p> <p>11 MS. PARFITT: Well, let's take a moment</p> <p>12 and let's see if we can --</p> <p>13 MS. BROWN: Why don't we go off the</p> <p>14 record for one second.</p> <p>15 THE VIDEOGRAPHER: The time is 9:25 a.m.</p> <p>16 We're going off the record.</p> <p>17 (Pause in the proceedings.)</p> <p>18 THE VIDEOGRAPHER: The time is 9:27 a.m.</p> <p>19 and we are back on the record.</p> <p>20 (Diette Exhibit No. 4 was marked</p> <p>21 for identification.)</p> <p>22 MS. PARFITT: Ready?</p> <p>23 THE VIDEOGRAPHER: Oh, yeah, we're on.</p> <p>24 MS. PARFITT: Okay. Thank you.</p> <p>25 BY MS. PARFITT:</p>
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<p>1 have a disconnect here. Are you referring to the</p> <p>2 7 of the reliance list?</p> <p>3 MS. PARFITT: I am. I'm sorry about</p> <p>4 that.</p> <p>5 THE WITNESS: Oh. Is it 7 of the -- the</p> <p>6 exhibit you gave me or is it part of what's my</p> <p>7 reliance list that's attached to my report?</p> <p>8 BY MS. PARFITT:</p> <p>9 Q What I have is your reliance list, and</p> <p>10 it's page 7 of your reliance list.</p> <p>11 A I got you.</p> <p>12 MS. BROWN: Got that. Okay.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q And I believe you have three Purdie --</p> <p>15 excuse me, two Purdie cites, one 2003 and one</p> <p>16 1995. Correct?</p> <p>17 A That's correct.</p> <p>18 Q Okay. Did you indeed review the Purdie</p> <p>19 article for purposes of your testimony here today?</p> <p>20 MS. BROWN: Objection to the form.</p> <p>21 THE WITNESS: I don't think I reviewed</p> <p>22 it for the purpose of my testimony, but I -- I</p> <p>23 included it because it's something I reviewed at</p> <p>24 some point prior to preparing the report.</p> <p>25 BY MS. PARFITT:</p>	<p>1 Q Dr. Diette, let me show you what's been</p> <p>2 marked as Plaintiffs' Exhibit No. 4 to the Diette</p> <p>3 deposition, and I'll represent to you -- sorry --</p> <p>4 I'll represent to you that this is the --</p> <p>5 MS. BROWN: Thank you.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q -- an article by Dr. Purdie entitled</p> <p>8 "Ovulation and Risk of Epithelial Ovarian Cancer"</p> <p>9 published in the International Journal of Cancer</p> <p>10 in 2003. Do you see that?</p> <p>11 A I do.</p> <p>12 Q All right. If I can direct your</p> <p>13 attention to page 231 of that article.</p> <p>14 MS. PARFITT: Let's put it on the ELMO.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. And, Dr. Diette, I'll put it up</p> <p>17 on the overhead as well. About halfway down --</p> <p>18 there you go -- left-hand column, Dr. Purdie and</p> <p>19 authors state: "Thus, the latency period of more</p> <p>20 advanced malignant epithelial ovarian cancer could</p> <p>21 be estimated to be approximately 30 to 40 years."</p> <p>22 Did I read that correctly?</p> <p>23 A You read it fine.</p> <p>24 Q All right. Do you agree or disagree</p> <p>25 that the latency period of more advanced malignant</p>

12 (Pages 42 to 45)

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<p style="text-align: right;">Page 46</p> <p>1 epithelial ovarian cancer can be estimated to be 2 approximately 30 to 40 years? 3 A Well, I think, you know -- so there's no 4 way for me to know for sure, right, but could 5 be -- it seems like a pretty safe statement 6 because it could be more, it could be less. 7 It's also an incomplete sentence, right, 8 in the sense that when you talk about the latency, 9 you talk about the latency between a particular 10 kind of exposure. I mean, in this context, right, 11 there may have other -- there may be other ways 12 people use that word, but in this context it's the 13 time from the exposure to the development of the 14 disease. So there's no exposure mentioned in that 15 sentence, so it's a little -- a little loose, you 16 know. 17 MS. PARFITT: All right. Move to strike 18 that last part of your statement. 19 BY MS. PARFITT: 20 Q Okay. Dr. Diette, do you agree that 21 it's imperative to develop public health programs 22 that either reduce the incidence or detect ovarian 23 cancer at an earlier stage? 24 A It's an agreeable statement. 25 Q Okay. In developing public health</p>	<p style="text-align: right;">Page 48</p> <p>1 BY MS. PARFITT: 2 Q Sure. And, you know, that might be -- 3 that might be fair. So let me go for a third try. 4 Okay? 5 A Okay. 6 Q Do you develop public health programs 7 for Johns Hopkins? 8 A I'm trying to think -- I would say 9 generally, no. I mean -- 10 Q It's not part of your role. 11 MS. BROWN: Well, let him finish. I'm 12 sorry. 13 THE WITNESS: But I don't know -- I 14 mean, I don't know what -- I mean that's a pretty 15 broad topic, which is what's a public health 16 program. So I'm just thinking like, for example, 17 you know, I've done work with asthma in -- in the 18 inner city nearby. 19 BY MS. PARFITT: 20 Q Correct. 21 A And we certainly have a program, you 22 know, that deals with -- with that. I wouldn't 23 say I've developed it as a public health program 24 per se but as a -- as a research program. But, 25 you know, where public health starts and stops,</p>
<p style="text-align: right;">Page 47</p> <p>1 programs, does -- in order to set up preventive 2 programs, detection programs, does that include 3 getting information about whatever the putative 4 exposure may be to individuals who may be 5 susceptible to them? 6 MS. BROWN: Objection to the form of the 7 question. 8 MS. PARFITT: Let me strike that 9 question completely. It was a lousy question. 10 All right. 11 THE WITNESS: It was -- 12 MS. PARFITT: And I'm going to agree 13 with counsel on that. How about that? 14 THE WITNESS: It was below average. It 15 wasn't lousy. 16 BY MS. PARFITT: 17 Q Sure. Okay. 18 When one develops a public health 19 program in order to alert individuals about a 20 public health issue, what is the manner, let's 21 say, in your department to do that? 22 MS. BROWN: Objection to the form of the 23 question. 24 THE WITNESS: I'm not sure what we're 25 talking about. I mean --</p>	<p style="text-align: right;">Page 49</p> <p>1 I'm not exactly sure. 2 Q Fair enough. 3 All right. Talcum powder products are 4 widely available, correct? 5 MS. BROWN: Objection to the form of the 6 question. 7 THE WITNESS: You know, they -- I 8 guess -- so anyway, I'm an epidemiologist, so when 9 somebody says something like that, like when you 10 say it, like I'm thinking like to whom or for whom 11 or where or when or something. I mean there's 12 sort of like a time and place and something else 13 more to that. I think it's a common product, but 14 I don't -- I don't know what it means to be widely 15 available. 16 BY MS. PARFITT: 17 Q All right. Did you ever ask Johnson & 18 Johnson or their attorneys a question with regard 19 to how many bottles of Johnson & Johnson's Baby 20 Powder they distribute each year in America? 21 MS. BROWN: Objection to the form of the 22 question. 23 THE WITNESS: I have not asked that. 24 BY MS. PARFITT: 25 Q Okay. Similarly, have you ever asked</p>

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<p style="text-align: right;">Page 50</p> <p>1 Johnson & Johnson how many bottles of their Shower</p> <p>2 to Shower they distributed?</p> <p>3 A No.</p> <p>4 MS. BROWN: Same objection.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q All right. Have you ever purchased</p> <p>7 talcum powder products?</p> <p>8 A I -- I don't do the shopping. You know,</p> <p>9 and so it -- like, I don't -- I don't buy anything</p> <p>10 at the store.</p> <p>11 Q Okay. Fair enough.</p> <p>12 Are you aware of the fact that Johnson &</p> <p>13 Johnson continues to sell their talcum powder</p> <p>14 products?</p> <p>15 A I wasn't aware that they weren't. I</p> <p>16 mean, I don't know where I would get that from,</p> <p>17 but as best as I can tell.</p> <p>18 Q All right. Have you ever looked at the</p> <p>19 back of a Johnson & Johnson's Baby Powder product</p> <p>20 to see what it says about its usage --</p> <p>21 MS. BROWN: Objection.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q -- and direction?</p> <p>24 MS. BROWN: Excuse me. Objection to the</p> <p>25 form of the question.</p>	<p style="text-align: right;">Page 52</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Okay. Let me show you what I'll have</p> <p>3 marked as Exhibit --</p> <p>4 MS. PARFITT: Where are we?</p> <p>5 MR. ROSEN: Five.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q -- 5. And I'll represent to you,</p> <p>8 Dr. Diette, that this is a bottle of Johnson's</p> <p>9 Baby Powder, and we'll have it marked as Exhibit</p> <p>10 No. 5.</p> <p>11 (Diette Exhibit No. 5 was marked</p> <p>12 for identification.)</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Now, my understanding is that you are</p> <p>15 trained, skilled, and have expertise in pulmonary</p> <p>16 medicine, correct?</p> <p>17 A Among other things.</p> <p>18 Q And I didn't mean to limit your</p> <p>19 expertise. Okay.</p> <p>20 If you will, let me show -- pass to you</p> <p>21 the Exhibit No. 5, and ask that you turn it to the</p> <p>22 back. Look at the bottle.</p> <p>23 MS. BROWN: Counsel, before he does</p> <p>24 that, will you put -- represent on the record</p> <p>25 where this bottle that you've marked as Exhibit 5</p>
<p style="text-align: right;">Page 51</p> <p>1 THE WITNESS: It's possible that I have</p> <p>2 years ago, but not -- not recently.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q Nothing recent.</p> <p>5 How about since you were retained by</p> <p>6 Johnson & Johnson as an expert, have you ever</p> <p>7 looked at a bottle of Johnson & Johnson's Baby</p> <p>8 Powder or Shower to Shower?</p> <p>9 MS. BROWN: Same objection.</p> <p>10 THE WITNESS: No. I've seen pictures,</p> <p>11 you know, in different settings, but I haven't --</p> <p>12 I haven't seen a bottle of it or looked at it.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Okay. Do you have an understanding as</p> <p>15 to whether or not Johnson & Johnson's Baby Powder</p> <p>16 or the Shower to Shower contains a warning on its</p> <p>17 product against use in the genital area to avoid</p> <p>18 ovarian cancer?</p> <p>19 MS. BROWN: Objection to the form.</p> <p>20 THE WITNESS: I don't know whether they</p> <p>21 do or don't. But I'm also not, you know, skilled</p> <p>22 in warnings. So I wouldn't -- I mean, I -- even</p> <p>23 if it said something, I wouldn't necessarily be</p> <p>24 the person to tell you whether that's a warning or</p> <p>25 not.</p>	<p style="text-align: right;">Page 53</p> <p>1 came from and when it was purchased and by whom?</p> <p>2 MS. PARFITT: Counsel, I'm asking the</p> <p>3 questions. I just represent that it is a bottle</p> <p>4 of Johnson & Johnson's Baby Powder purchased from</p> <p>5 a store.</p> <p>6 MS. MILLER: Michelle, I'm trying</p> <p>7 really, really hard not to say a word today.</p> <p>8 MS. PARFITT: Sure.</p> <p>9 MS. MILLER: I know that I'll annoy</p> <p>10 you --</p> <p>11 MS. PARFITT: Oh, no, you're not.</p> <p>12 MS. MILLER: -- but it's not Johnson &</p> <p>13 Johnson's Baby Powder. It's Johnson's Baby</p> <p>14 Powder, and you keep saying it wrong.</p> <p>15 MS. PARFITT: That's fine. That's fine.</p> <p>16 MS. MILLER: And I think for the record,</p> <p>17 it's important. It's a product by JJCI, as you</p> <p>18 know.</p> <p>19 MS. PARFITT: That's fine.</p> <p>20 MS. MILLER: So we just need</p> <p>21 Johnson's --</p> <p>22 MS. PARFITT: Okay. And why don't we --</p> <p>23 whenever I -- since I'm sure I won't remember all</p> <p>24 that, why don't we just reflect for the record</p> <p>25 that when I say Johnson & Johnson's Baby Powder,</p>

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<p>1 that it's Johnson's Baby Powder. Okay?</p> <p>2 MS. BROWN: And just to get my -- my</p> <p>3 objection on the record to what you marked as</p> <p>4 Exhibit 5, we have no representation of when this</p> <p>5 was bought, by whom it was bought.</p> <p>6 With that, Dr. Diette, here is</p> <p>7 Exhibit 5.</p> <p>8 MS. PARFITT: Thank you.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q All right, Dr. Diette, look at the back</p> <p>11 of that. Do you see that there's a little picture</p> <p>12 that looks like a little baby with an X on it?</p> <p>13 A I do.</p> <p>14 MS. BROWN: Objection to the form.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. Okay. What does that say on the</p> <p>17 back of the product?</p> <p>18 A It says: "Warning: Keep powder away</p> <p>19 from child's face to avoid inhalation, which can</p> <p>20 cause breathing problems. Avoid contact with the</p> <p>21 eyes. For external use only."</p> <p>22 Q Okay. And at the bottom of that</p> <p>23 product, does it happen to say what's contained in</p> <p>24 it?</p> <p>25 MS. BROWN: Objection to the form of the</p>	<p>1 expert work for them?</p> <p>2 MS. BROWN: Objection to the form.</p> <p>3 THE WITNESS: I believe so, yeah.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay. Had you ever worked for Johnson &</p> <p>6 Johnson or any of their entities prior to 2017 in</p> <p>7 any type of litigation?</p> <p>8 MS. BROWN: Same objection.</p> <p>9 THE WITNESS: I -- I don't think so. I</p> <p>10 would say almost certainly no.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Okay. Since your retention in 2017, did</p> <p>13 Johnson & Johnson, their medical department, their</p> <p>14 regulatory department, science department, ever</p> <p>15 ask that you take a look at the back of the</p> <p>16 product, Johnson's Baby Powder, for purposes of</p> <p>17 giving an opinion as to what scientific and</p> <p>18 medical information should be on that product?</p> <p>19 MS. BROWN: Objection to the form of the</p> <p>20 question.</p> <p>21 THE WITNESS: I would be the wrong kind</p> <p>22 of expert for that. I mean I'm not a warnings</p> <p>23 expert, so it wouldn't -- wouldn't make any sense</p> <p>24 for anybody to ask me that question.</p> <p>25 BY MS. PARFITT:</p>
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<p>1 question.</p> <p>2 THE WITNESS: It has a line called</p> <p>3 "Ingredients," which says "Talc, fragrance."</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay. Dr. Diette, you've been retained</p> <p>6 by Johnson & Johnson since when, for purposes of</p> <p>7 the ovarian cancer cases?</p> <p>8 MS. BROWN: Objection. Form. Do you</p> <p>9 mean the Ingham case or do you mean the MDL?</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Well, let me clarify.</p> <p>12 When were you first -- it's a fair</p> <p>13 question -- when were you first retained by</p> <p>14 Johnson & Johnson to represent them in either</p> <p>15 mesothelioma cases or ovarian cancer cases?</p> <p>16 MS. BROWN: Objection to the form. He</p> <p>17 is an expert witness on behalf of Johnson &</p> <p>18 Johnson. He is not here representing anyone.</p> <p>19 THE WITNESS: That honestly sounds like</p> <p>20 Ms. Brown's job, I mean, but -- but I guess to try</p> <p>21 to answer your question, the -- I was first asked</p> <p>22 to review the epidemiology in 2017.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Okay. And was that the first time that</p> <p>25 Johnson & Johnson had asked you to provide any</p>	<p>1 Q I'm not asking you about the adequacy of</p> <p>2 the warning. I'm asking you about your expertise</p> <p>3 as a pulmonary medicine expert with regard to</p> <p>4 inhalation issues as contained on the back of that</p> <p>5 product.</p> <p>6 A It still wouldn't make any sense. I</p> <p>7 wouldn't be the person to ask that to.</p> <p>8 Q Dr. Diette, whether or not it makes</p> <p>9 sense to you or not, my question is simply this:</p> <p>10 Yes or no, has Johnson & Johnson asked your</p> <p>11 opinion at any point in time with regard to what</p> <p>12 kind of scientific and medical information should</p> <p>13 be on the back of their powder?</p> <p>14 MS. BROWN: Objection. Answered three</p> <p>15 times.</p> <p>16 THE WITNESS: They and everybody else in</p> <p>17 the world has not asked me to do anything like</p> <p>18 that ever.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q Okay. And they, Johnson & Johnson, has</p> <p>21 never asked you to -- your opinion with regard to</p> <p>22 the inhalation warning; is that correct?</p> <p>23 MS. BROWN: Objection. Counsel, we've</p> <p>24 been through this like six times.</p> <p>25 THE WITNESS: I think it's the same</p>

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<p style="text-align: right;">Page 58</p> <p>1 warning we're talking about, right?</p> <p>2 BY MS. PARFITT:</p> <p>3 Q The one that's on the back, yeah.</p> <p>4 A So it's still -- still the same.</p> <p>5 Q Okay. And just for the record, we're</p> <p>6 going to put on the ELMO -- thank you. Just go</p> <p>7 ahead and see if we can get that on there. Okay.</p> <p>8 (Counsel conferring.)</p> <p>9 BY MS. PARFITT:</p> <p>10 Q And again, for clarity of the record,</p> <p>11 what we've been talking about is on -- the child</p> <p>12 with the X over the nose and mouth and the warning</p> <p>13 that is to the far right, correct?</p> <p>14 MS. BROWN: Objection to the form.</p> <p>15 THE WITNESS: I was with you until you</p> <p>16 said "to the far right." I don't know --</p> <p>17 BY MS. PARFITT:</p> <p>18 Q To the right of the baby.</p> <p>19 A Oh, I see. I'm sorry.</p> <p>20 Q Yeah, no problem.</p> <p>21 A Yeah. No, that's --</p> <p>22 Q That's what we're talking about.</p> <p>23 A It's to the right of the baby, yeah.</p> <p>24 Q Okay. Very good. All right.</p> <p>25 Dr. Diette, as a scientist and a</p>	<p style="text-align: right;">Page 60</p> <p>1 you have who have a different opinion with regard</p> <p>2 to the causality of talcum powder products and</p> <p>3 ovarian cancer?</p> <p>4 MS. BROWN: Objection to the form.</p> <p>5 THE WITNESS: Well, I've seen like, for</p> <p>6 example, the expert reports that are -- that are</p> <p>7 part of this matter and some of the deposition</p> <p>8 transcripts. So -- so, yes, I mean I've seen what</p> <p>9 they've said.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Okay. And from your review of those</p> <p>12 expert reports, do you understand that many of</p> <p>13 those scientists and epidemiologists are</p> <p>14 individuals who treat women who have been</p> <p>15 diagnosed for ovarian cancer? Do you understand</p> <p>16 that?</p> <p>17 MS. BROWN: Objection. Lacks</p> <p>18 foundation, calls for speculation.</p> <p>19 THE WITNESS: So I saw that there were</p> <p>20 some GYN oncologists involved. I don't remember</p> <p>21 the count of them, but I saw there were GYN</p> <p>22 oncologists, both on the defense and the</p> <p>23 plaintiffs' side.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Okay. And the GYN oncologists would be</p>
<p style="text-align: right;">Page 59</p> <p>1 clinician, do you have a belief or opinion that</p> <p>2 women should be informed of even a potential risk</p> <p>3 of using talcum powder products on their genital</p> <p>4 area?</p> <p>5 MS. BROWN: Objection.</p> <p>6 THE WITNESS: Not based on what I've</p> <p>7 reviewed.</p> <p>8 BY MS. PARFITT:</p> <p>9 Q Okay. Is it your opinion that there is</p> <p>10 no risk of ovarian cancer from the long-term use</p> <p>11 of talcum powder products?</p> <p>12 MS. BROWN: Objection. Form.</p> <p>13 THE WITNESS: I -- I don't see evidence</p> <p>14 that there's a -- so I'm an epidemiologist, so the</p> <p>15 way I talk about things might be a little</p> <p>16 different than the way you're asking it. But</p> <p>17 there's not sufficient evidence to say that it's a</p> <p>18 cause of ovarian cancer.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q Okay. And we'll talk about that in a</p> <p>21 little bit.</p> <p>22 Do you have an understanding as to</p> <p>23 whether there are other scientists and</p> <p>24 epidemiologists who have reviewed the same</p> <p>25 scientific and epidemiological information that</p>	<p style="text-align: right;">Page 61</p> <p>1 the practice of medicine that treats women for</p> <p>2 reproductive diseases and cancers like ovarian</p> <p>3 cancer, correct?</p> <p>4 MS. BROWN: Objection.</p> <p>5 THE WITNESS: They -- they would be the</p> <p>6 ones that provide treatment for the GYN cancers.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Okay. You're a pulmonologist, correct?</p> <p>9 A I am.</p> <p>10 Q All right.</p> <p>11 A And again, among other things.</p> <p>12 Q Understood.</p> <p>13 MS. BROWN: Let him finish, Counsel, he</p> <p>14 wasn't done.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q My -- it's a simple question, are you a</p> <p>17 pulmonologist?</p> <p>18 MS. BROWN: Wait, but he was still</p> <p>19 answering. You cut him off. Let him finish.</p> <p>20 MS. PARFITT: Doc -- I withdraw that</p> <p>21 question.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Are you a pulmonologist?</p> <p>24 A I am a pulmonologist.</p> <p>25 Q All right. As a pulmonologist, do you</p>

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<p style="text-align: right;">Page 62</p> <p>1 treat and care for women -- treat and care and</p> <p>2 provide gynecological and oncological care to</p> <p>3 women who have been diagnosed with ovarian cancer?</p> <p>4 MS. BROWN: Objection to the form.</p> <p>5 THE WITNESS: Mostly, no, although</p> <p>6 I'll just -- there was a lot in your question,</p> <p>7 right, so that --</p> <p>8 BY MS. PARFITT:</p> <p>9 Q You want me to break it down?</p> <p>10 MS. BROWN: Let him finish first, and</p> <p>11 then you can follow up. He has to be allowed to</p> <p>12 answer your question.</p> <p>13 MS. PARFITT: Oh, absolutely, but if</p> <p>14 it's unclear -- that was one of the --</p> <p>15 THE WITNESS: I didn't say it was</p> <p>16 unclear. I just said it -- it's complicated, so</p> <p>17 there's more than -- it's not just a simple</p> <p>18 answer.</p> <p>19 MS. PARFITT: Let me withdraw the</p> <p>20 question.</p> <p>21 MS. BROWN: Wait, Counsel, he's not</p> <p>22 done.</p> <p>23 Dr. Diette, you finish your answer, and</p> <p>24 then counsel, of course, will follow up.</p> <p>25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 64</p> <p>1 that.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Okay. What is your understanding of the</p> <p>4 testing that's been performed by Johnson & Johnson</p> <p>5 on their talcum powder products?</p> <p>6 MS. BROWN: Objection. That's overly</p> <p>7 broad.</p> <p>8 THE WITNESS: Well, like the type --</p> <p>9 MS. BROWN: You mean internal, external,</p> <p>10 third party, FDA?</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Do you understand the question?</p> <p>13 A I was actually going to say something</p> <p>14 similar to what Ms. Brown said but less</p> <p>15 sophisticated.</p> <p>16 I mean what I meant was, were you asking</p> <p>17 about like the kinds of tests that were done or --</p> <p>18 or things of that sort? I just -- I just know,</p> <p>19 generally speaking, that there has been testing</p> <p>20 done.</p> <p>21 Q Sure. Let me make it very simple.</p> <p>22 Are you aware of studies -- strike that.</p> <p>23 Have you seen studies done by Johnson &</p> <p>24 Johnson that tested and evaluated their talcum</p> <p>25 powder products for the presence of asbestos?</p>
<p style="text-align: right;">Page 63</p> <p>1 Q Okay. Go ahead.</p> <p>2 A Thank you.</p> <p>3 Q Sure.</p> <p>4 A So, you know, I wouldn't be the person</p> <p>5 who prescribes chemotherapy or provides the</p> <p>6 surgery. Part of my work is as an intensive care</p> <p>7 doc in the oncology center, and so I'll see people</p> <p>8 with every kind of cancer possible and provide</p> <p>9 some of the care to them.</p> <p>10 I see people in my clinic that have, you</p> <p>11 know, pulmonary consequences of some of their</p> <p>12 treatment for ovarian cancer. And so it's -- it's</p> <p>13 not a straightforward yes or no that I do or don't</p> <p>14 participate, but I don't do the -- the GYN onc</p> <p>15 part of that care.</p> <p>16 Q All right. Have you in your practice of</p> <p>17 pulmonary medicine ever diagnosed a woman with</p> <p>18 ovarian cancer?</p> <p>19 A I can't remember ever doing that.</p> <p>20 Q All right. Now, Dr. Diette, are you</p> <p>21 aware of whether or not -- strike that.</p> <p>22 Are you aware that Johnson & Johnson has</p> <p>23 tested their talcum powder products?</p> <p>24 MS. BROWN: Objection to the form.</p> <p>25 THE WITNESS: I have some awareness of</p>	<p style="text-align: right;">Page 65</p> <p>1 MS. BROWN: Same objection.</p> <p>2 THE WITNESS: I don't think I've seen</p> <p>3 anything from Johnson & Johnson, per se.</p> <p>4 Is that what -- is that what you're</p> <p>5 referring to?</p> <p>6 BY MS. PARFITT:</p> <p>7 Q That is, yes.</p> <p>8 A Okay. Then not -- not that I'm aware</p> <p>9 of.</p> <p>10 Q All right. I saw where you looked at</p> <p>11 the depositions of Drs. Longo and Rigler.</p> <p>12 MS. BROWN: Objection to the form.</p> <p>13 THE WITNESS: Is that in a different</p> <p>14 case?</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Good question. You have their</p> <p>17 depositions listed as part of the materials</p> <p>18 reviewed and relied upon. Have you read those?</p> <p>19 MS. BROWN: Objection.</p> <p>20 If you want to refresh yourself on your</p> <p>21 reliance list, I'm sure counsel will point you to</p> <p>22 the page.</p> <p>23 MS. PARFITT: Absolutely.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Let me direct you to -- just bear with</p>

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<p style="text-align: right;">Page 66</p> <p>1 me one second. I apologize here.</p> <p>2 Okay. It's -- your reference materials</p> <p>3 reviewed and considered start on -- or in</p> <p>4 Appendix B of your report.</p> <p>5 Do you see that?</p> <p>6 A I don't see Longo and Rigler.</p> <p>7 Q Okay. At the very top, it has</p> <p>8 "Materials Reviewed and Considered by Gregory</p> <p>9 Diette," and the second item under "Expert</p> <p>10 References" says "Expert report of William Longo</p> <p>11 and Mark Rigler."</p> <p>12 Do you see that?</p> <p>13 A Oh, I do, yeah. So I see Longo, and I'm</p> <p>14 just --</p> <p>15 Q Do you see Rigler? He's right after</p> <p>16 that. It says William --</p> <p>17 A Oh, got you.</p> <p>18 MS. BROWN: Counsel, these are reports.</p> <p>19 I thought your question was about a deposition.</p> <p>20 MS. PARFITT: That's a -- that's a fair</p> <p>21 objection.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Have you read the expert report of</p> <p>24 William Longo and Mark Rigler?</p> <p>25 A So, because I see there's a date on it</p>	<p style="text-align: right;">Page 68</p> <p>1 Q But my question --</p> <p>2 MS. PARFITT: And noted.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q My question to you is, sitting here</p> <p>5 today, what I need to know -- and if it's no,</p> <p>6 that's a fine answer. If it's yes, that's a fine</p> <p>7 answer.</p> <p>8 Have you read the expert report of</p> <p>9 Drs. Longo and Rigler dated November 14, 2018?</p> <p>10 If you did, I'm not -- I'm not --</p> <p>11 MS. BROWN: Objection to the form. I</p> <p>12 think he answered that.</p> <p>13 Counsel, I think what you're really</p> <p>14 after is, is he relying on that to form his</p> <p>15 opinion.</p> <p>16 MS. PARFITT: Actually, I'm not. That's</p> <p>17 a good question, but I'm not asking that.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q Did you read the report?</p> <p>20 A So I -- I'm not sure if I read this one</p> <p>21 with this particular date.</p> <p>22 Q That's fine.</p> <p>23 A But wait, wait, wait. But, you know, if</p> <p>24 it's on here, because that's what it reminds me</p> <p>25 of, I don't have a specific memory for this matter</p>
<p style="text-align: right;">Page 67</p> <p>1 of November 14th, 2018 --</p> <p>2 Q Correct.</p> <p>3 A -- I know I've seen at least a few of</p> <p>4 Dr. Longo's reports, and I -- I think they're the</p> <p>5 same over and over again. So I -- if I -- if I'm</p> <p>6 not mistaken, I don't think I would have reread it</p> <p>7 like, you know, specifically for this matter if it</p> <p>8 looked the same as others. I think I probably</p> <p>9 just like flipped through it to see what it was --</p> <p>10 was there generally.</p> <p>11 Q All right. So I understand your answer,</p> <p>12 is your testimony that you don't recall</p> <p>13 specifically reviewing the November 14th, 2018</p> <p>14 expert report of Dr. Longo's and Rigler?</p> <p>15 MS. BROWN: Objection to the form,</p> <p>16 misstates his testimony.</p> <p>17 MS. MILLER: So can I say something?</p> <p>18 Because I was involved in that, I think that every</p> <p>19 item with respect to litigation that we sent to</p> <p>20 Dr. Diette, which would have been depositions or</p> <p>21 expert reports, was put on the list because it was</p> <p>22 sent to him. I --</p> <p>23 MS. PARFITT: Oh, and I understand. I</p> <p>24 appreciate that.</p> <p>25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 69</p> <p>1 because I've been reading some of these things for</p> <p>2 other matters as well. So I -- you know, I don't</p> <p>3 remember whether -- whether I read that particular</p> <p>4 one, but if it looked like other ones that I had,</p> <p>5 I would have, you know, touched it, opened it,</p> <p>6 looked to see what was in there, and then not read</p> <p>7 every word of it. But I don't remember which way</p> <p>8 it worked.</p> <p>9 Q Sitting here today, are you able to tell</p> <p>10 me the results of Dr. Longo and Rigler's testing</p> <p>11 of Johnson & Johnson's talcum powder products as</p> <p>12 reflected in their expert reports of November 14,</p> <p>13 2018?</p> <p>14 MS. BROWN: Objection to the form.</p> <p>15 THE WITNESS: I don't remember the</p> <p>16 details, but I could -- I could look that up and</p> <p>17 pull -- pull out what I saw.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q Did you mark it?</p> <p>20 MS. BROWN: Objection to the form.</p> <p>21 THE WITNESS: Oh, you mean like with</p> <p>22 highlights?</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Mm-hmm. Yes, with highlights.</p> <p>25 A Sorry. I thought you were talking about</p>

18 (Pages 66 to 69)

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<p style="text-align: right;">Page 70</p> <p>1 marking exhibits, I'm thinking like that's not 2 what I do. So, no -- so I don't know. 3 Q All right. 4 A This particular one, I might have 5 highlighted an earlier one or -- or even not. And 6 the only reason I say that is because his reports 7 tend to have an awful lot of like sort of like 8 testing data in the -- in the back of it, and 9 there's not a lot of like words, you know, to 10 read. So there's not a lot to really highlight 11 for me. I mean, you know what I mean? It's kind 12 of succinct in terms of like the opinion part, and 13 then there's a whole bunch of scientific stuff 14 that's somebody else's field. 15 Q Understood. And I think what I'm 16 getting at is for purposes of the opinions you are 17 presenting to the jury in this case, are you 18 relying on the test results of Dr. Longo's and 19 Rigler's that are contained in not only their 20 November 14th -- contained in their November 14th, 21 2018 report? 22 MS. BROWN: And objection. 23 Counsel, you said "jury." I assume you 24 mean for purposes of this Daubert hearing, is he 25 relying on the Rigler and Longo report of</p>	<p style="text-align: right;">Page 72</p> <p>1 wouldn't say I rely on it in the sense that it's 2 an underpinning of an opinion or something like 3 that. 4 Q All right. Do you have an understanding 5 then that Drs. Longo and Rigler found the presence 6 of asbestos in the talcum powder products they 7 tested? 8 MS. BROWN: Objection to the form of the 9 question. 10 THE WITNESS: My -- my understanding is 11 they say they found it, but I don't -- I don't 12 know the fact of whether they found it or not. 13 BY MS. PARFITT: 14 Q Okay. Did -- from your read or not read 15 of Drs. Longo and Rigler -- strike that. 16 Did Drs. Longo and Rigler find 17 asbestiform fibers in the tests done of Johnson & 18 Johnson's product, talcum powder products? 19 MS. BROWN: Objection to the form. 20 THE WITNESS: I guess I need to know 21 what we're talking about if you say "asbestiform 22 fibers," because I thought your question before 23 was asbestos. 24 BY MS. PARFITT: 25 Q It was.</p>
<p style="text-align: right;">Page 71</p> <p>1 November 14th, 2018. 2 BY MS. PARFITT: 3 Q For purposes of the opinions that you 4 have provided in your expert report and I assume 5 will present to Judge Wolfson sometime in July, 6 are you relying on the information that's 7 contained in the expert report of Dr. Longo and 8 Rigler, November 14, 2018? 9 A I wouldn't use the word "rely." I would 10 say aware of, but not -- I'm not relying on it. 11 Q And let me explore that, because this is 12 the only time I will have a chance to talk to you 13 before that Daubert hearing. 14 A Sure. 15 Q Are you, for purposes of your opinion 16 that you're sharing -- will share with me today 17 and will share with the court in July, relying on 18 any of the test results of Drs. Longo and Rigler 19 contained in their reports of November 14, 2018? 20 A Yeah, I think the way I said it is 21 exactly right, because to me "rely on" has some -- 22 there's some legal connotation for that, right. 23 And so it doesn't -- it doesn't inform 24 my opinion, but I'm aware of what his general 25 position has been. And so -- but I don't -- I</p>	<p style="text-align: right;">Page 73</p> <p>1 A And are you expecting me to -- to say 2 that that's two different things, or is it just 3 another way of you trying to ask the same 4 question? 5 Q How do you define "asbestiform fibers"? 6 MR. LOCKE: Objection. 7 MS. BROWN: Objection to the form of the 8 question. 9 THE WITNESS: Well, I -- I understand 10 some the terminology, but I'm not a mineralogist. 11 Right. So I -- I can tell you -- I think I have 12 to diverge a little bit to answer your question, 13 if I can, just to say that -- unless you don't 14 want me to. Feel free to -- 15 MS. BROWN: No, you should answer the 16 question -- 17 THE WITNESS: Okay. 18 MS. BROWN: -- as honestly and 19 truthfully and accurately as you can. 20 THE WITNESS: Because asbestos -- I 21 mean, asbestos in terms of at least its 22 commercial, you know, forms is something that's 23 in -- that's in asbestiform fiber, right. It's in 24 asbestiform habit. And so I think, you know, for 25 me to understand the minerals, when we're talking</p>

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<p style="text-align: right;">Page 74</p> <p>1 about asbestos, we're talking about a particular</p> <p>2 kind of mineral that's in a particular form or</p> <p>3 habit.</p> <p>4 And so I -- I think when you're talking</p> <p>5 about an asbestiform fiber, there's some</p> <p>6 redundancy there in a way, right, which is that</p> <p>7 that's a description that you could apply to</p> <p>8 something that other people would call asbestos.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q All right. Fine. Thank you.</p> <p>11 Has Johnson & Johnson provided you with</p> <p>12 any testing that they performed on their product?</p> <p>13 MS. BROWN: Objection.</p> <p>14 BY MS. PARFITT:</p> <p>15 Q Shower to Shower or Johnson's Baby</p> <p>16 Powder.</p> <p>17 MS. BROWN: Objection.</p> <p>18 THE WITNESS: I don't think I have seen</p> <p>19 anything.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Did you ever ask Johnson & Johnson to</p> <p>22 see any of the testing that they performed on</p> <p>23 their own talcum powder products?</p> <p>24 MS. BROWN: Objection. Asked and</p> <p>25 answered.</p>	<p style="text-align: right;">Page 76</p> <p>1 would not alter your analysis, and I assume</p> <p>2 opinions, with regard to talcum powder products</p> <p>3 causing ovarian cancer.</p> <p>4 A That's in my report?</p> <p>5 Q Yes.</p> <p>6 A Can we flip to that?</p> <p>7 Q Sure. Why don't you go to page 3.</p> <p>8 And if I may, it's at the bottom,</p> <p>9 paragraph 6.</p> <p>10 A I'm with you, yeah.</p> <p>11 Q Okay. And it says: "To the extent</p> <p>12 plaintiffs' expert opined that asbestos is an</p> <p>13 accessory mineral present in cosmetic talc that</p> <p>14 causes ovarian cancer, this theory would not alter</p> <p>15 the analysis because the existing epidemiological</p> <p>16 literature regarding talc use would</p> <p>17 necessarily" --</p> <p>18 MS. BROWN: You're reading it --</p> <p>19 MS. PARFITT: Beg your pardon?</p> <p>20 MS. BROWN: You read it wrong. Perineal</p> <p>21 talc use.</p> <p>22 MS. PARFITT: Oh, I'm sorry. Perineal.</p> <p>23 Thank you.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q -- "perineal talc use would necessarily</p>
<p style="text-align: right;">Page 75</p> <p>1 THE WITNESS: I have not.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Okay. Dr. Diette, are you aware that</p> <p>4 there are generic talcum powder products being</p> <p>5 sold in the marketplace today that contain an</p> <p>6 ovarian cancer warning for individuals who use it</p> <p>7 in their genital area?</p> <p>8 MS. BROWN: Objection to the form --</p> <p>9 THE WITNESS: I don't --</p> <p>10 MS. BROWN: -- lacks foundation, calls</p> <p>11 for speculation.</p> <p>12 THE WITNESS: I don't know one way or</p> <p>13 the other.</p> <p>14 BY MS. PARFITT:</p> <p>15 Q Okay. Has Johnson & Johnson shared that</p> <p>16 information with you?</p> <p>17 MS. BROWN: Same objections.</p> <p>18 THE WITNESS: Well, if they had, I'd be</p> <p>19 aware of it, right? I mean --</p> <p>20 BY MS. PARFITT:</p> <p>21 Q I would think.</p> <p>22 A Yeah. So it has to be no. Yeah.</p> <p>23 Q Okay. You state in your -- you state in</p> <p>24 your expert report that the presence of asbestos</p> <p>25 as an accessory mineral present in cosmetic talc</p>	<p style="text-align: right;">Page 77</p> <p>1 account for the presence of any asbestos in the</p> <p>2 products used in both studies."</p> <p>3 Did I now read that correctly, with</p> <p>4 counsel's correction?</p> <p>5 A Yeah, you're -- you've got it right now.</p> <p>6 Q Okay. What do you mean by that</p> <p>7 statement?</p> <p>8 A So what I -- what I mean generally is</p> <p>9 that I've reviewed the -- what I think is the</p> <p>10 whole epidemiology on the -- on the topic, and the</p> <p>11 studies themselves don't break down or don't do</p> <p>12 analyses of what the talcum powder is or what it</p> <p>13 consists of. So to the extent that they've</p> <p>14 studied talcum powder, to me whatever is in talcum</p> <p>15 powder is baked into the epidemiology. And so</p> <p>16 whether asbestos is a fact that it's in there or</p> <p>17 it's a fact that it's not doesn't really change</p> <p>18 how to interpret those studies.</p> <p>19 Is that what you're asking?</p> <p>20 Q Mm-hmm.</p> <p>21 A Okay.</p> <p>22 Q Mm-hmm. Is asbestos a carcinogen?</p> <p>23 A It is.</p> <p>24 Q We're going to come back to that.</p> <p>25 Let me just get on a little bit further</p>

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<p>1 on here.</p> <p>2 Are you going to be giving an opinion in</p> <p>3 this case that Johnson & Johnson's talcum powder</p> <p>4 products contain asbestos?</p> <p>5 A No.</p> <p>6 Q You will not?</p> <p>7 A I will not.</p> <p>8 Q Have you made an assumption then for</p> <p>9 purposes of your opinion that Johnson's -- that</p> <p>10 Johnson & Johnson's talcum powder products do not</p> <p>11 contain asbestos?</p> <p>12 A I -- no, I haven't made that assumption.</p> <p>13 I -- I recognize that there's a debate about that,</p> <p>14 and I don't have the expertise to sort through</p> <p>15 what's right about that debate.</p> <p>16 Q All right. Assume that Johnson &</p> <p>17 Johnson's talcum powder products contain asbestos,</p> <p>18 would that place consumers that use the product in</p> <p>19 needless danger?</p> <p>20 MS. BROWN: Objection. Counsel, that's</p> <p>21 an incomplete hypothetical. Is that the same talc</p> <p>22 that's in the epi?</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Can you answer the question?</p> <p>25 MS. PARFITT: And please don't coach the</p>	<p>1 all over the world, right. And so everything</p> <p>2 comes down to dose in any case, right. So for me</p> <p>3 to be concerned about it, you'd have to show me</p> <p>4 that there's a sufficient dose that a person gets</p> <p>5 in order to raise the risk of whatever it is that</p> <p>6 you're talking about.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Let me ask you this: Assume Johnson &</p> <p>9 Johnson's talcum powder products has asbestos in</p> <p>10 it. Are you with me?</p> <p>11 A I am, yeah.</p> <p>12 Q All right. Would it be imprudent for</p> <p>13 Johnson & Johnson to sell its talcum powder</p> <p>14 products to consumers to use it in their</p> <p>15 genital -- on their genital areas?</p> <p>16 MS. BROWN: I object to this line of</p> <p>17 question, Counsel. Are you divorcing your</p> <p>18 hypothetical from the epidemiology he has reviewed</p> <p>19 and is here to talk about?</p> <p>20 MS. PARFITT: He didn't answer the</p> <p>21 question, Counsel. Counsel, if he understands --</p> <p>22 he understood the last question, it's the same.</p> <p>23 Thank you.</p> <p>24 MS. BROWN: I object to the entire line</p> <p>25 of questioning.</p>
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<p>1 witness.</p> <p>2 MS. BROWN: Objection to the incomplete</p> <p>3 hypothetical.</p> <p>4 THE WITNESS: So, anyway, so the</p> <p>5 needless part, I think -- I'm not sure if you need</p> <p>6 that in your question or whether it changes how I</p> <p>7 would answer it. I think the general issue is</p> <p>8 whether or not there's a risk or whether there's a</p> <p>9 danger. And from what I can tell from reading the</p> <p>10 literature, that there's not a risk of -- did you</p> <p>11 say "ovarian cancer" in your question?</p> <p>12 BY MS. PARFITT:</p> <p>13 Q Correct.</p> <p>14 A Yeah, I don't see that there's a -- a</p> <p>15 risk of ovarian cancer from the literature.</p> <p>16 Q Assume for purposes of my question that</p> <p>17 Johnson & Johnson's talcum powder products has</p> <p>18 asbestos in it, would it be imprudent and not</p> <p>19 reasonable for Johnson & Johnson to sell that</p> <p>20 product to its customers, yes or no?</p> <p>21 MS. BROWN: Objection to the incomplete</p> <p>22 hypothetical.</p> <p>23 THE WITNESS: So I think, you know, it</p> <p>24 isn't a yes or no, right? I mean, because it's --</p> <p>25 if you're talking about asbestos, there's asbestos</p>	<p>1 BY MS. PARFITT:</p> <p>2 Q Please.</p> <p>3 A If we're talking about what exists in</p> <p>4 the world right now, I -- I don't see any issue</p> <p>5 with it.</p> <p>6 Q All right. Do you know who</p> <p>7 Dr. Nicholson is?</p> <p>8 A Which -- which Nicholson?</p> <p>9 Q Susan Nicholson.</p> <p>10 A I'm not sure. Is she an expert in --</p> <p>11 Q She's not. She's actually the -- and</p> <p>12 I'll represent to you, the chief medical officer</p> <p>13 for Johnson & Johnson.</p> <p>14 A Oh, I don't know her.</p> <p>15 Q Okay. Let me represent to you that</p> <p>16 Dr. Nicholson, who is a medical officer for</p> <p>17 Johnson & Johnson, was deposed in this case, this</p> <p>18 same case that we're in together, you and I. Are</p> <p>19 you aware of that?</p> <p>20 A Only because you said so.</p> <p>21 Q Okay. And the deposition that was taken</p> <p>22 of Dr. Nicholson was a deposition that was taken</p> <p>23 wherein she -- we call it a 30(b)(6). That means</p> <p>24 she represents the voice of the company that she</p> <p>25 works for. Understand?</p>

21 (Pages 78 to 81)

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<p style="text-align: right;">Page 82</p> <p>1 MS. BROWN: Objection to the form of the 2 question. 3 THE WITNESS: I understand what you 4 said. I don't know what I -- if I understand what 5 that means. 6 MS. PARFITT: Okay. All right. Let me 7 have marked as Exhibit -- I believe it's 8 Exhibit No. 6 that we're on. 9 (Diette Exhibit No. 6 was marked 10 for identification.) 11 MS. BROWN: And, Counsel, if you're 12 going to ask him questions about Dr. Nicholson's 13 deposition that he has not reviewed, we need to at 14 least have a full copy of the deposition here. 15 Thanks. 16 MS. PARFITT: I believe you have -- 17 MS. BROWN: And you should take as long 18 as you need to review it to answer any questions 19 counsel might have. 20 MS. PARFITT: Okay. And, Counsel, I'll 21 get you that -- I don't have a copy -- 22 MS. BROWN: We have -- I mean your 23 colleague just -- 24 MS. PARFITT: We have just one. I'm 25 just saying we just have one. I don't have one</p>	<p style="text-align: right;">Page 84</p> <p>1 Q Okay. At the top, if I may, it says -- 2 line 2: "Well" -- and I'll represent to you that 3 I was one of the attorneys that took 4 Dr. Nicholson's deposition. 5 The question is: "Well, if your 6 products contain asbestos, would you agree with me 7 that that impacts the safety of the product?" 8 Answer: "Absolutely, yes." 9 Next question: "Would you agree that 10 Johnson & Johnson has a zero tolerance policy with 11 regard to having asbestos in their talcum powder 12 products?" 13 The answer: "Yeah, that is correct." 14 Next question: "In fact, as a 15 representative of the company, it's your position 16 that your Johnson & Johnson's talcum powder 17 products should not contain asbestos; is that 18 correct?" 19 "That's correct -- that is correct." 20 Next question: "And you would agree 21 with me that if your talcum powder products had 22 asbestos in them, it would place the consumers 23 that use your product in needless danger, 24 correct?" 25 "It could, yes."</p>
<p style="text-align: right;">Page 83</p> <p>1 for you. 2 MS. BROWN: As long as the doctor has 3 time to review it -- you know he hasn't seen this 4 before. If you're going to ask him questions 5 about it, he needs to read it. 6 MS. PARFITT: Just one. 7 BY MS. PARFITT: 8 Q Dr. Nich- -- or Dr. Diette, let me 9 direct your attention to page 37. 10 A Okay. 11 Q And specifically line 2, and let me read 12 it. We'll put it up on the ELMO. 13 MS. BROWN: Counsel, while you're doing 14 that, I'm going to object to taking one page out 15 of Dr. Nicholson's deposition that the doctor has 16 not reviewed and asking questions out of context. 17 And if he needs to read the whole deposition to 18 answer your question, he will need to do that. 19 MS. PARFITT: Counsel, please not -- 20 let's not coach. 21 MS. BROWN: And I'm objecting on the 22 record to the improper questioning with snippets 23 of somebody else's deposition. 24 MS. PARFITT: Okay. 25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 85</p> <p>1 Next question on page 48 of that same 2 deposition -- 3 MS. BROWN: Counsel, I'm sorry, but your 4 pages are not matching up to what we've been 5 handed. Can you just direct us -- and we're -- in 6 the snippet you gave us, I can't find this. 7 THE WITNESS: I don't have 48. Mine 8 goes to 41. 9 MS. BROWN: Yeah, mine says 37, 37, 37. 10 THE WITNESS: Maybe here in the whole 11 thing? 12 MR. HEASLIP: And mine is 46 through 53. 13 MS. PARFITT: Okay. 14 MS. BROWN: This is not what you're 15 reading, so it's impossible to follow. 16 Were you able to follow that, Doctor? 17 MS. PARFITT: We have it on the 18 overhead. I think -- 19 MR. ROSEN: I go to -- I go to 41. 20 MS. BROWN: Yeah, well, he needs to have 21 it in front of him. We don't have a copy. 22 MS. PARFITT: Well, let's do this. I 23 have an overhead and an ELMO. So let's keep 24 going. Why don't you read the screen. 25 Do you need me to go back over those</p>

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<p style="text-align: right;">Page 86</p> <p>1 questions?</p> <p>2 MS. BROWN: But, Counsel, that's not</p> <p>3 even a transcript. What is that?</p> <p>4 MS. PARFITT: It's --</p> <p>5 MS. MILLER: How are you going to mark</p> <p>6 that as an exhibit?</p> <p>7 MS. PARFITT: I'm going to put an</p> <p>8 exhibit sticker on it, and I'm going to put it in</p> <p>9 as representative pages from the Nicholson</p> <p>10 deposition.</p> <p>11 MS. BROWN: Can he find it in the large</p> <p>12 copy?</p> <p>13 MR. ROSEN: Would you mind passing</p> <p>14 back Exhibit 6 that we handed --</p> <p>15 THE WITNESS: Oh. This is all of your</p> <p>16 36's. That's a whole bundle of the same thing.</p> <p>17 But I would like to get the 36-page</p> <p>18 back --</p> <p>19 MS. PARFITT: Sure.</p> <p>20 THE WITNESS: -- if we're going to talk</p> <p>21 about it.</p> <p>22 MS. PARFITT: Absolutely. I want you to</p> <p>23 have actually 37, and you need -- here we go.</p> <p>24 MS. BROWN: This is the complete set?</p> <p>25 MS. PARFITT: Yes, I'm assuming.</p>	<p style="text-align: right;">Page 88</p> <p>1 Did I read all that correctly?</p> <p>2 A You did.</p> <p>3 Q All right. Do you -- so you disagree</p> <p>4 with Dr. Nicholson; is that correct?</p> <p>5 MS. BROWN: Objection to the form.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 MS. BROWN: Misstates his testimony.</p> <p>8 THE WITNESS: I don't -- I don't agree</p> <p>9 or disagree. I mean, I -- I honestly don't know</p> <p>10 who she is other than what you just said. But --</p> <p>11 but it sounds like she's articulating a policy for</p> <p>12 the company, which I think is her right -- her</p> <p>13 right to do that and to express those opinions.</p> <p>14 BY MS. PARFITT:</p> <p>15 Q Okay. All right.</p> <p>16 Okay. Now, counsel provided for us in</p> <p>17 advance of this deposition a copy of your CV. So</p> <p>18 let me --</p> <p>19 THE WITNESS: Would it -- would it be a</p> <p>20 good time just to refill coffee? Is that okay?</p> <p>21 MS. PARFITT: Sure. And I should have</p> <p>22 said that. Any time you need a break --</p> <p>23 THE WITNESS: No, I know.</p> <p>24 MS. PARFITT: -- you holler.</p> <p>25 THE WITNESS: Thank you. I appreciate</p>
<p style="text-align: right;">Page 87</p> <p>1 MS. BROWN: You have that in front of</p> <p>2 you?</p> <p>3 THE WITNESS: I do.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q And, Dr. Diette, if you have any trouble</p> <p>6 reading any of that -- or you can also look up on</p> <p>7 the ELMO that's being displayed.</p> <p>8 MS. BROWN: Thank you.</p> <p>9 MS. PARFITT: Okay. Yeah, sorry.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Again, page 48, line 14.</p> <p>12 Do you have that there, Doctor, in front</p> <p>13 of you?</p> <p>14 A I do.</p> <p>15 Q Okay.</p> <p>16 "Q. You would agree, Dr. Nicholson, if</p> <p>17 Johnson & Johnson's Baby Powder indeed had</p> <p>18 asbestos in it, it would be imprudent and not</p> <p>19 reasonable for Johnson & Johnson to sell it to its</p> <p>20 consumers?"</p> <p>21 "A. I would agree with that.</p> <p>22 "Q. Thank you.</p> <p>23 "A. I would not support Johnson &</p> <p>24 Johnson selling a product that contained</p> <p>25 asbestos."</p>	<p style="text-align: right;">Page 89</p> <p>1 that.</p> <p>2 MS. PARFITT: You're very welcome.</p> <p>3 THE VIDEOGRAPHER: The time is 10:07</p> <p>4 p.m. We're going off the record.</p> <p>5 (Recess.)</p> <p>6 THE VIDEOGRAPHER: The time is</p> <p>7 10:20 a.m., and we're back on the record.</p> <p>8 BY MS. PARFITT:</p> <p>9 Q Dr. Diette, are you still --</p> <p>10 THE VIDEOGRAPHER: Microphone, Counsel.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Are you good?</p> <p>13 A All set. Thank you.</p> <p>14 Q All right. Dr. Diette, if asbestos was</p> <p>15 found to be in talcum powder products -- strike</p> <p>16 that.</p> <p>17 Would the presence of asbestos in talcum</p> <p>18 powder products provide evidence to support the</p> <p>19 hypothesis that talcum powder products -- strike</p> <p>20 that.</p> <p>21 Would the presence of asbestos in talcum</p> <p>22 powder products provide biologically plausible</p> <p>23 evidence to support the hypothesis that talcum</p> <p>24 powder products can cause ovarian cancer?</p> <p>25 MR. LOCKE: Objection.</p>

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<p style="text-align: right;">Page 90</p> <p>1 MS. BROWN: Objection to the form of the</p> <p>2 question.</p> <p>3 THE WITNESS: You would have to qualify</p> <p>4 it, right, because I -- if you're talking about</p> <p>5 like -- even like, you know, one fiber or</p> <p>6 something would be quite different than if there's</p> <p>7 a sufficient amount in order to -- to cause a</p> <p>8 disease, right. So it -- it always comes down to</p> <p>9 dose in terms of what you're talking about.</p> <p>10 So it's -- all by itself, I don't think</p> <p>11 that that question is answerable.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q Can one fiber of asbestos alone cause</p> <p>14 cancer?</p> <p>15 MS. BROWN: Objection to the form.</p> <p>16 THE WITNESS: It's -- it's so impossible</p> <p>17 to think that it would, because we all have</p> <p>18 asbestos in our lungs, and there's a background</p> <p>19 amount of asbestos in the world that if one fiber</p> <p>20 could do it, I think we would all have cancer. So</p> <p>21 I -- I think somebody could say that, but I don't</p> <p>22 think it would be true.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q You certainly don't think it's true; is</p> <p>25 that correct?</p>	<p style="text-align: right;">Page 92</p> <p>1 papers that have been either accepted or published</p> <p>2 since then. There's probably some talks and</p> <p>3 things. The -- the grant award section I'm sure</p> <p>4 needs updating.</p> <p>5 Q Okay. It looks, on the far right of</p> <p>6 that CV, that it's got a June 2017 date; is that</p> <p>7 correct?</p> <p>8 A It is.</p> <p>9 Q All right. Has there been a curriculum</p> <p>10 vitae prepared by you since June of 2017?</p> <p>11 A No.</p> <p>12 Q All right. Where would I get these</p> <p>13 additional articles and speeches? Do you have</p> <p>14 them in a -- contained in one particular place?</p> <p>15 A No. Where -- where you could get the</p> <p>16 articles would be on PubMed, and if you just did a</p> <p>17 PubMed search with my name, you would find them</p> <p>18 all.</p> <p>19 For speeches, I don't actually have a</p> <p>20 repository, so it's going to take me some work to</p> <p>21 actually sort of populate that part of the CV.</p> <p>22 Q Are you -- do you have any intention of</p> <p>23 updating your CV?</p> <p>24 A Yes. Can I give you an extra sentence</p> <p>25 or two?</p>
<p style="text-align: right;">Page 91</p> <p>1 A Oh, for sure, yeah.</p> <p>2 Q Okay. Let me mark at this time a</p> <p>3 copy -- a copy of your curriculum vitae, and we'll</p> <p>4 have it marked as exhibit -- Exhibit 7.</p> <p>5 (Diette Exhibit No. 7 was marked</p> <p>6 for identification.)</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Do you have that in front of you?</p> <p>9 A I do.</p> <p>10 Q Okay. Who prepared that curriculum</p> <p>11 vitae?</p> <p>12 A Well, not one person. This is an</p> <p>13 iterative exercise over time. So it's -- I mean,</p> <p>14 me in the sense, although not as the person, you</p> <p>15 know, typing the words, but it's -- you know, it's</p> <p>16 my -- my information on here. And I've had</p> <p>17 different administrative assistants who have --</p> <p>18 who have helped to sort of shape it.</p> <p>19 Q Is it current?</p> <p>20 A No.</p> <p>21 Q It's not?</p> <p>22 A It's not.</p> <p>23 Q All right. What additions or deletions</p> <p>24 would you make to your curriculum vitae?</p> <p>25 A For the most part, I'd add a bunch of</p>	<p style="text-align: right;">Page 93</p> <p>1 Q Sure.</p> <p>2 A Okay. So I sure want to. The stakes</p> <p>3 are low for me at this point. This is our</p> <p>4 Department of Medicine format CV, which we use for</p> <p>5 promotion purposes, for the most part. I've been</p> <p>6 promoted to professor, which there's no other rank</p> <p>7 to get promoted to. And so it's not really that</p> <p>8 urgent for me to -- to change that.</p> <p>9 Then on top of that, my administrative</p> <p>10 assistant went out on maternity leave, and then I</p> <p>11 didn't want to swamp her with this when she came</p> <p>12 back.</p> <p>13 Q That was nice.</p> <p>14 A And literally just last week, she took a</p> <p>15 new job, a better job but in a different place.</p> <p>16 So long answer, yeah, I want to, but</p> <p>17 it's not going to happen really soon.</p> <p>18 Q Okay. So your current academic</p> <p>19 appointment at Johns Hopkins University, is that a</p> <p>20 professor of medicine, is that correct, Division</p> <p>21 of Pulmonary and Critical Care?</p> <p>22 A Yeah, and I think it's called Pulmonary,</p> <p>23 Criteria Care and Sleep Medicine now. We just --</p> <p>24 we just changed the name recently.</p> <p>25 Q And sleep medicine?</p>

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<p style="text-align: right;">Page 94</p> <p>1 A And sleep, yeah.</p> <p>2 Q All right. Are you still within the</p> <p>3 Department of Epidemiology?</p> <p>4 A Yes.</p> <p>5 Q All right. Are you still an associate</p> <p>6 professor of medicine in epi and environmental</p> <p>7 health?</p> <p>8 A No, that's a typo somewhere. I don't</p> <p>9 know where you saw that, but -- oh, probably in my</p> <p>10 report. But, no, I'm -- the professor label</p> <p>11 carries across all the -- the different entities.</p> <p>12 Q So you're no longer an associate</p> <p>13 professor.</p> <p>14 A Right. Professor of whatever it is that</p> <p>15 I'm a professor of.</p> <p>16 Q All right. Your board certification is</p> <p>17 in pulmonary and critical care?</p> <p>18 A It's in internal medicine and pulmonary</p> <p>19 medicine.</p> <p>20 Q You're not a member of the American</p> <p>21 College of Epidemiology, correct?</p> <p>22 A No.</p> <p>23 Q Your undergraduate degree was in</p> <p>24 English?</p> <p>25 A English and economics.</p>	<p style="text-align: right;">Page 96</p> <p>1 hospital as well.</p> <p>2 Q All right. So if someone were going on</p> <p>3 the website to look at the hospital, the medical</p> <p>4 school, medical center, this is what they would</p> <p>5 see. And look over to the far right, and it has</p> <p>6 "Expertise." Do you see that?</p> <p>7 A I do.</p> <p>8 Q All right. Is -- it reads: "Expertise:</p> <p>9 Asthma, chronic obstructive pulmonary disease</p> <p>10 (COPD), pulmonary" -- excuse me -- "pulmonary</p> <p>11 disease, and critical care medicine, pulmonary</p> <p>12 medicine."</p> <p>13 Is that correct?</p> <p>14 A It is correct.</p> <p>15 Q All right. Is there anything you want</p> <p>16 to add with regard to your expertise?</p> <p>17 MS. BROWN: Objection to the form of the</p> <p>18 question.</p> <p>19 THE WITNESS: So I honestly don't know</p> <p>20 what this is. I mean, I don't doubt that it comes</p> <p>21 from Hopkins, but it's not something I look at.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Okay.</p> <p>24 A If you -- well, no, just one second.</p> <p>25 Because if you look at the bottom, it says</p>
<p style="text-align: right;">Page 95</p> <p>1 Q Okay. And then post-medical school, you</p> <p>2 received a MHS in public health; is that correct?</p> <p>3 A Well, it was in epidemiology.</p> <p>4 Q Okay.</p> <p>5 A I only just say that because there is a</p> <p>6 degree in public health, and that's not what mine</p> <p>7 was called.</p> <p>8 Q Okay. Let me show you what we'll have</p> <p>9 marked as the Johns Hopkins Medicine website as --</p> <p>10 MS. PARFITT: What exhibit?</p> <p>11 MS. BROWN: 8.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q -- Exhibit 8?</p> <p>14 (Diette Exhibit No. 8 was marked</p> <p>15 for identification.)</p> <p>16 BY MS. PARFITT:</p> <p>17 Q All right. Do you have that in front of</p> <p>18 you?</p> <p>19 A I do.</p> <p>20 Q All right. Now, this is for the Johns</p> <p>21 Hopkins Medical School; is that correct, or</p> <p>22 medical center?</p> <p>23 A So I don't know. You know, the top says</p> <p>24 "Johns Hopkins Medicine," which is a broader label</p> <p>25 that includes the medical school and probably the</p>	<p style="text-align: right;">Page 97</p> <p>1 "Request an appointment." So this looks like some</p> <p>2 kind of place that somebody could go and find a</p> <p>3 call-in number to get an appointment for -- for a</p> <p>4 doctor.</p> <p>5 Q Okay.</p> <p>6 A So I think it's -- I don't know. I</p> <p>7 could add all kinds of things, but I don't -- I</p> <p>8 don't know what the format is for this. Like I</p> <p>9 don't know if there is a word limit.</p> <p>10 Q Sorry.</p> <p>11 A I don't know -- I don't know what the</p> <p>12 purpose of this is.</p> <p>13 Q All right. The second line says:</p> <p>14 "Research interests," and it states:</p> <p>15 "Environmental impacts on lung disease,</p> <p>16 epidemiology of airway disease and chronic</p> <p>17 obstructive pulmonary disease, asthma."</p> <p>18 Did I read that correctly?</p> <p>19 A You did.</p> <p>20 Q Does that accurately reflect your</p> <p>21 current research interests?</p> <p>22 MS. BROWN: Objection. Form.</p> <p>23 THE WITNESS: Well, it's some, but it's</p> <p>24 so incomplete. You know, it's obviously just a</p> <p>25 couple of snippets that somebody chose to put on</p>

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<p style="text-align: right;">Page 98</p> <p>1 this -- on this page. 2 BY MS. PARFITT: 3 Q Okay. Well, I will represent to you 4 that if one chose to go on the Johns Hopkins 5 Medicine website, this is how they hold you out to 6 the -- to the world, so to speak. 7 MS. BROWN: Objection to the speech. Is 8 there a question? 9 THE WITNESS: So -- 10 MS. PARFITT: Counsel -- 11 MS. BROWN: There's no question. 12 MS. PARFITT: -- please. 13 MS. BROWN: Is there a question? 14 MS. PARFITT: Yes. 15 MS. BROWN: What is it? 16 BY MS. PARFITT: 17 Q Is this how -- is this information 18 correct, Dr. Diette? 19 A Oh, the information is correct. 20 Q Okay. 21 A It's very incomplete. 22 Q Okay. Let me show you now what we'll 23 have marked as Exhibit 9. 24 (Diette Exhibit No. 9 was marked 25 for identification.)</p>	<p style="text-align: right;">Page 100</p> <p>1 it to see if it's accurate or not, but there's -- 2 there's certainly more about me than just those 3 couple of -- 4 Q Okay. Well, you know, that's a good 5 point, and I missed that. So thank you for 6 bringing that to our attention. 7 Let's look at that sec- -- second page 8 of the website for Johns Hopkins Medical Center. 9 MR. TISI: Counsel, that is Exhibit 8. 10 MS. PARFITT: And it is Exhibit 8. 11 Thank you. 12 Okay. Let's put that up there. 13 BY MS. PARFITT: 14 Q And there's a category that says 15 "Background"; is that correct? 16 A It is. 17 Q All right. Now, it states: 18 "Dr. Gregory Diette is a professor of medicine at 19 the Johns Hopkins University School of Medicine. 20 He holds a joint appointment in the Department of 21 Epidemiology in the Johns Hopkins Bloomberg School 22 of Public Health." Hashtag, "His areas of 23 clinical expertise include asthma and obstructive 24 lung disease." 25 Did I read that correctly?</p>
<p style="text-align: right;">Page 99</p> <p>1 THE WITNESS: Can I just -- just 2 clarify? 3 BY MS. PARFITT: 4 Q There's no question pending right now. 5 A I want to clarify my last -- 6 MS. BROWN: But if you want -- 7 BY MS. PARFITT: 8 Q Your counsel will have a chance to -- to 9 talk with you. 10 MS. BROWN: Whoa, Counsel. Are you 11 going to take the position on the record that the 12 witness can't clarify any -- 13 MS. PARFITT: No, I'm not doing that 14 all. 15 MS. BROWN: Well, that was his request, 16 and he wanted to -- 17 BY MS. PARFITT: 18 Q What do you need to do, Doctor? I'm 19 sorry. 20 A Oh, well, I just -- because we were 21 talking about this front page, and I didn't 22 realize there were other pages here. This still 23 isn't complete, but there's a whole lot here more 24 about me than just what was on that front page. I 25 just wanted to point to all that. I haven't read</p>	<p style="text-align: right;">Page 101</p> <p>1 A You did. 2 Q Okay. Is that correct? 3 A That -- that it includes those two 4 diseases? 5 Q Yes. 6 A It does include that. 7 Q Okay. And the third paragraph reads: 8 "His research interests include environmental 9 impacts on lung disease, epidemiology of airway 10 disease, and chronic obstructive pulmonary 11 disease." 12 Did I read that correctly? 13 A You did. 14 Q All right. And does that reflect some 15 of your research interests? 16 A It does. 17 Q All right. Now, let's move over -- and 18 thank you for correcting me on that. 19 Now, I will represent to you that 20 Exhibit 9 is from the website from the Bloomberg 21 School of Public Health. 22 Do you have that in front of you? 23 A I do. 24 Q All right. Now, if one was to go onto 25 the website for the Bloomberg School of Public</p>

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<p style="text-align: right;">Page 102</p> <p>1 Health, this is the type of information they would 2 receive, Dr. Diette. 3 Look down at the "Overview." Do you see 4 that? 5 A I do. 6 Q Okay. It says -- 7 MS. PARFITT: Let's get that up on the 8 ELMO. 9 BY MS. PARFITT: 10 Q All right. Do you see under "Overview," 11 it says: "My research focuses on identifying 12 factors that cause or provoke asthma. We have 13 been interested especially in air pollutants," 14 parens, "particulate matter, NO2, secondhand 15 smoke," close parens, "and allergens," parens, 16 "including mouse," close parens, "that are 17 especially problematic in inner city homes. We 18 are studying the effects of these pollutants and 19 allergens on inflammation and oxidative stress. 20 More recently, we have begun examining how dietary 21 patterns, especially a Western diet style -- a 22 Western-style diet, may increase susceptibility to 23 inhalable pollutants and allergens." 24 Did I read that correctly? 25 A You did.</p>	<p style="text-align: right;">Page 104</p> <p>1 patients who come to you are experiencing? 2 MS. BROWN: Objection to the form. 3 THE WITNESS: And I'll do my best, and 4 then if it's not what you're looking for, please 5 just ask me to clarify. 6 I -- I see probably, you know, almost 7 every single kind of medical problem there is 8 because I -- I attend in so many different 9 locations within the Hopkins system. So meaning 10 that I do work in the intensive care unit where 11 it's every kind of medical problem you could 12 imagine, it just happens to be the sickest of the 13 sick. So it could be any -- any organ system, or 14 not even an organ system, but all sorts of 15 illnesses. 16 In the pulmonary clinic, I see -- I 17 certainly see people with asthma and COPD, but I 18 see pretty much any kind of pulmonary disease and 19 get referrals for things that aren't pulmonary 20 diseases. They -- they may be somebody who's got 21 a -- a symptom that turns out not to be a 22 pulmonary disease. 23 In the oncology center, when I attend 24 there, I see every kind of cancer patient that at 25 least that Hopkins sees.</p>
<p style="text-align: right;">Page 103</p> <p>1 Q Okay. And then again, under your 2 "Research Interests, it states: "Epidemiology of 3 lung diseases, asthma, COPD" -- 4 And what's COPD? 5 A Chronic obstructive pulmonary disease. 6 Q -- "outcomes, environmental," and then 7 it says, "Particulate matter, allergens and health 8 disparities." 9 Did I read that correctly? 10 A You did. 11 Q All right. Does that represent some of 12 your research interests? 13 A It does represent some. 14 Q Okay. You are a clinician? 15 A True. 16 Q All right. What is the profile of the 17 types of patients that you see in your practice? 18 MS. BROWN: Form. 19 THE WITNESS: You want me to just take a 20 stab at it? Because I'm not sure -- is profile -- 21 MS. BROWN: If you don't understand the 22 question, I'm sure counsel will clarify it. 23 MS. PARFITT: I will, sure. 24 BY MS. PARFITT: 25 Q What is the nature of the diseases that</p>	<p style="text-align: right;">Page 105</p> <p>1 And then I'm also lucky enough to attend 2 on the general internal medicine service, and so 3 there it's really everything, it's all comers. 4 And so it ranges from basically head-to-toe kind 5 of medicine. 6 BY MS. PARFITT: 7 Q Okay. Now, if I arrived at -- for in -- 8 I guess you said the intensive care clinic, and I 9 had a gynecological problem, would I see you? 10 MS. BROWN: Objection to the form. 11 THE WITNESS: So there's no intensive 12 care clinic, just to be clear. Like a clinic is 13 an outpatient setting. So our intensive care unit 14 is an inpatient setting for critically ill people. 15 BY MS. PARFITT: 16 Q Okay. 17 A So you might or might not end up seeing 18 me, because if we're -- the way that the program 19 works is that -- so, for example, if somebody is 20 pregnant, just giving an example, if it's an early 21 pregnancy, then those patients would end up in our 22 medical ICU. If it's a later pregnancy, then they 23 would go to the -- the obstetrics unit to their -- 24 their own particular unit. And then you might see 25 me if I was consulted into that unit, whether or</p>

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<p style="text-align: right;">Page 106</p> <p>1 not you were in our -- our unit or not.</p> <p>2 Q So if I came in with a gynecological</p> <p>3 problem, they might call you -- you, who are a</p> <p>4 pulmonologist, they might call you in to consult</p> <p>5 with me?</p> <p>6 MS. BROWN: Objection to the form of the</p> <p>7 question and the tone.</p> <p>8 THE WITNESS: Well, I am picking up the</p> <p>9 tone, which I -- which I think -- I mean, I know</p> <p>10 you're trying to make a point here. And the</p> <p>11 question as you asked it is -- the answer is, of</p> <p>12 course. But I think what you're trying to get at</p> <p>13 is would they have asked me to come deal with</p> <p>14 their pregnancy, for example, and I wouldn't be</p> <p>15 the person dealing with their pregnancy. I would</p> <p>16 be dealing with something else.</p> <p>17 BY MS. PARFITT:</p> <p>18 Q Okay. All right. Is it fair to say</p> <p>19 that your practice primarily deals with</p> <p>20 individuals who have pulmonary and lung disease</p> <p>21 conditions?</p> <p>22 MS. BROWN: Objection.</p> <p>23 THE WITNESS: I think if you dial back</p> <p>24 and listen to what I said for those other answers,</p> <p>25 you would be pretty clear that it isn't just that.</p>	<p style="text-align: right;">Page 108</p> <p>1 certainly interested in pollutants.</p> <p>2 Q Okay. And more recently, you've</p> <p>3 expressed a research interest in dietary patterns</p> <p>4 particularly, and especially a Western diet and</p> <p>5 how that might increase susceptibility to</p> <p>6 inhalable pollutants; is that correct?</p> <p>7 A True.</p> <p>8 MS. BROWN: Form.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q Are you -- have you published recently</p> <p>11 on that?</p> <p>12 A I'm sure there's stuff that's come out.</p> <p>13 Q Well, I only have your CV from 2017, so</p> <p>14 I'll represent that I'm not seeing something on</p> <p>15 that CV.</p> <p>16 Is there something you've done recently?</p> <p>17 A Yeah, it's a couple of years ago.</p> <p>18 Q Okay.</p> <p>19 A I mean the best way to find stuff would</p> <p>20 be on PubMed.</p> <p>21 Q All right. You've been retained to</p> <p>22 serve as an expert for Johnson & Johnson, correct?</p> <p>23 MS. BROWN: Form.</p> <p>24 THE WITNESS: That's correct.</p> <p>25 BY MS. PARFITT:</p>
<p style="text-align: right;">Page 107</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Okay. Well, I would include asthma in</p> <p>3 that as well.</p> <p>4 MS. BROWN: Same objection.</p> <p>5 THE WITNESS: Well, include it, but I</p> <p>6 mean -- but, you know, when I'm on the general</p> <p>7 internal medicine service, I'm not seeing mostly</p> <p>8 asthma. I might be seeing somebody with diabetes</p> <p>9 or a heart attack or pelvic inflammatory disease,</p> <p>10 you know, to name a GYN problem. I mean it's the</p> <p>11 whole gamut from head to toe.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q Is it fair to say your research in</p> <p>14 public health focuses on factors that cause and</p> <p>15 provoke asthma?</p> <p>16 MS. BROWN: Objection to the form of the</p> <p>17 question.</p> <p>18 THE WITNESS: It's a focus.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q Is it fair to say that you have a</p> <p>21 particular interest in air pollutants, and that</p> <p>22 includes secondhand smoke and mouse allergens?</p> <p>23 A I agree with most of what you said, but</p> <p>24 not literally the way you said it, because I don't</p> <p>25 think mouse allergen's a pollutant. So I'm</p>	<p style="text-align: right;">Page 109</p> <p>1 Q Okay. Do you know what the -- do you</p> <p>2 have an understanding of what the allegations are</p> <p>3 against Johnson & Johnson?</p> <p>4 MS. BROWN: Objection to the form.</p> <p>5 THE WITNESS: Which -- which ones?</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Do you know why you're -- Johnson &</p> <p>8 Johnson is being sued?</p> <p>9 MS. BROWN: Objection.</p> <p>10 Counsel, are you asking a legal</p> <p>11 question?</p> <p>12 MS. PARFITT: No.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Do you have any understanding of the</p> <p>15 allegations or the nature of the lawsuit against</p> <p>16 Johnson & Johnson, the company that's retained you</p> <p>17 to provide expert legal testimony?</p> <p>18 MS. BROWN: Same objection.</p> <p>19 THE WITNESS: I think, generally</p> <p>20 speaking, what I understand is that there's an</p> <p>21 allegation that talcum powder causes ovarian</p> <p>22 cancer.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Okay. Do you have an understanding of</p> <p>25 the allegations against Imerys?</p>

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<p>1 MS. BROWN: Objection.</p> <p>2 THE WITNESS: I don't have any separate</p> <p>3 understanding.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay. Do you know who Imerys are -- is</p> <p>6 or are?</p> <p>7 A I'm aware that it's a supply company of</p> <p>8 some sort, but I don't know much more about them.</p> <p>9 Q All right. And do you have an</p> <p>10 understanding of the allegations against the</p> <p>11 Personal Care Products Corporation --</p> <p>12 MS. BROWN: Objection.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q -- otherwise known as the PCPC?</p> <p>15 MS. BROWN: Objection. Calls for</p> <p>16 speculation.</p> <p>17 THE WITNESS: I don't --</p> <p>18 MR. LOCKE: Objection.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q You don't.</p> <p>21 A I don't know who that is.</p> <p>22 Q All right. Have you ever seen a</p> <p>23 complaint in this case?</p> <p>24 MS. BROWN: Objection.</p> <p>25 BY MS. PARFITT:</p>	<p>1 through it quickly and just get a sense of what</p> <p>2 the case is about.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q And then what do you do with it?</p> <p>5 MS. BROWN: Form.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Do you keep it?</p> <p>8 A Oh, not forever. I mean if the case is</p> <p>9 over, then I destroy it with all the other</p> <p>10 materials.</p> <p>11 Q Well, this case is far from over.</p> <p>12 Have -- do you still have --</p> <p>13 MS. BROWN: Counsel, just ask the</p> <p>14 question.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q -- a copy of the complaint?</p> <p>17 MS. MILLER: You asked about a state</p> <p>18 court case.</p> <p>19 MS. PARFITT: No. I said was there --</p> <p>20 hey -- again, hey, ladies, I'm sorry, I think the</p> <p>21 two of you are going to have to agree who is going</p> <p>22 to com- -- who's going to complain -- who's going</p> <p>23 to object. One of you can object.</p> <p>24 MS. BROWN: Well, if you're going to</p> <p>25 complain, I'm going to object.</p>
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<p>1 Q And when I say "this case," I'm talking</p> <p>2 about this case of talcum powder products and</p> <p>3 ovarian cancer, be it in an MDL context or a state</p> <p>4 context.</p> <p>5 MS. BROWN: Same objection.</p> <p>6 MS. MILLER: With any complaint, any</p> <p>7 talcum --</p> <p>8 MS. PARFITT: Any -- yeah, has he ever</p> <p>9 seen a complaint in any talcum powder product and</p> <p>10 ovarian cancer case.</p> <p>11 MS. BROWN: Objection to the form.</p> <p>12 THE WITNESS: I'm sure I must have.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q You're sure you must have.</p> <p>15 Is it in the materials that you have</p> <p>16 reviewed for purposes of your -- your deposition</p> <p>17 today or for purposes of the report you prepared?</p> <p>18 A No.</p> <p>19 MS. BROWN: Objection.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Okay. If you have seen it, what have</p> <p>22 you done with it?</p> <p>23 MS. BROWN: Objection. Vague.</p> <p>24 THE WITNESS: Well, the same thing I do</p> <p>25 with any complaint, which is just to try to read</p>	<p>1 MS. PARFITT: Okay.</p> <p>2 MS. BROWN: Please just ask the</p> <p>3 question. No speeches.</p> <p>4 MS. PARFITT: Then, please, and I --</p> <p>5 listen, I think that we're getting at a crossroads</p> <p>6 here. One person gets to object. And let me</p> <p>7 remind you what the CMO says, because I know you</p> <p>8 know that --</p> <p>9 MS. BROWN: Counsel --</p> <p>10 MS. PARFITT: And I'm not admonishing.</p> <p>11 Let me finish, Counsel --</p> <p>12 MS. BROWN: Don't yell at me.</p> <p>13 MS. PARFITT: -- and then you can speak.</p> <p>14 MS. BROWN: You're raising your tone at</p> <p>15 me.</p> <p>16 MS. PARFITT: Well, the camera will --</p> <p>17 oh, please, don't be so condescending.</p> <p>18 MS. BROWN: Sure, it's going to reflect</p> <p>19 that you're raising your tone.</p> <p>20 MS. PARFITT: I hope -- I hope that the</p> <p>21 Judge sees this because we're probably --</p> <p>22 MS. BROWN: We are well aware of the</p> <p>23 CMO.</p> <p>24 MS. PARFITT: -- going to have to call</p> <p>25 him soon.</p>

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<p style="text-align: right;">Page 114</p> <p>1 MS. BROWN: We are complying with it. 2 We're happy to call the Judge. 3 MS. PARFITT: So the CMO says that you 4 get to say, "Objection. Form." That's what you 5 get to say. 6 You have a wonderful opportunity at the 7 end of this deposition to ask him as many 8 questions as you like, but for right now, my time, 9 my deposition. It's, "Objection. Form." And I 10 really would appreciate that courtesy. I will 11 give it to you, but I would appreciate getting it 12 back. So -- 13 MS. BROWN: And to be clear -- 14 MS. PARFITT: No, Counsel, no more 15 speeches. No more speeches. 16 MS. BROWN: You just made a speech, and 17 I'm going to respond -- 18 MS. PARFITT: No more speeches, Counsel. 19 My deposition. 20 MS. BROWN: No, Counsel. 21 MS. PARFITT: Not your deposition. 22 BY MS. PARFITT: 23 Q Next question I have -- 24 MS. PARFITT: No more questions, 25 Counsel. You want me to depose you?</p>	<p style="text-align: right;">Page 116</p> <p>1 THE WITNESS: Can you say it again? 2 BY MS. PARFITT: 3 Q Sure. 4 A Yeah. 5 Q Have you ever been provided 6 gynecological care or treatment for a woman who 7 has been diagnosed with ovarian cancer? 8 A So there's just a couple of things 9 there, and I think maybe I heard it wrong. 10 Did you say been provided care? 11 Q Have you ever provided -- 12 A Provided. Okay. I'm sorry. I thought 13 you said "been provided." 14 Q No, no, no, no. 15 MS. MILLER: You did say that. 16 THE WITNESS: I thought it sounded like 17 did I get care. I was like -- 18 MS. MILLER: You did -- 19 BY MS. PARFITT: 20 Q No, I -- I don't think you did. 21 A Yeah, right. 22 Q I know, that would have been a very 23 awkward question, wouldn't it? 24 Have you ever provided gynecological 25 care or treatment for a woman who has been</p>
<p style="text-align: right;">Page 115</p> <p>1 MS. BROWN: Counsel, no. You are 2 raising your tone. 3 MS. PARFITT: Counsel -- 4 MS. BROWN: You are yelling at me. 5 MS. PARFITT: -- you know what, I was 6 told a little bit earlier nobody could hear me. 7 So I have lifted my voice, and now I'm using my 8 stage voice. So now everyone can hear me, and now 9 I'm speaking too loud to you. 10 So I'm going to try -- you know, you 11 can't have it both ways. One speaker, one 12 objectioner. Next question. 13 MS. BROWN: The record will reflect that 14 you are making incessant speeches. Please -- 15 BY MS. PARFITT: 16 Q Are you an oncologist, Dr. Diette? 17 A I am not an oncologist. 18 Q Are you a radiation oncologist? 19 A No. 20 Q Are you a gynecologist? 21 A No. 22 Q Okay. Have you ever provided 23 gynecological care or treatment for a woman who 24 has been diagnosed with ovarian cancer? 25 MS. BROWN: Objection. Form.</p>	<p style="text-align: right;">Page 117</p> <p>1 diagnosed with ovarian cancer? 2 A Sure. And I think it goes back to some 3 of the things I said before where I see people in 4 the hospital who have ovarian cancer, and through 5 my training, you know, for medical school and 6 residency, that was part of our training also, 7 which was to rotate on services where people 8 had every -- every imaginable illness. 9 Q Okay. Well, your residency was how long 10 ago? 11 MS. BROWN: Objection. 12 THE WITNESS: My residency was 1990 to 13 1993. 14 BY MS. PARFITT: 15 Q Okay. So I'm not talking about what you 16 did in 1993, back in that period of time. 17 What I'm talking about is whether or not 18 you have actually provided gynecological care to a 19 woman who presented to you with ovarian cancer? 20 MS. BROWN: Objection to the form. 21 Asked and answered five times. 22 You can answer, Dr. Diette. 23 BY MS. PARFITT: 24 Q And by that, primary care. Not in a 25 consulting role but primary care.</p>

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<p style="text-align: right;">Page 118</p> <p>1 MS. BROWN: Same objection.</p> <p>2 THE WITNESS: I think I know your</p> <p>3 question, but could you be specific like --</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Sure.</p> <p>6 A -- like just an example, and then I'll</p> <p>7 know that we're talking about the same thing.</p> <p>8 Q Okay. Have you ever provided primary</p> <p>9 care, gynecological care or treatment for a woman</p> <p>10 who has been diagnosed with ovarian cancer?</p> <p>11 A So --</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: -- I'm not trying to</p> <p>14 criticize the question, but primary care sounds</p> <p>15 like something that a -- like a family</p> <p>16 practitioner or an internist would do. I think</p> <p>17 you mean something else, so --</p> <p>18 BY MS. PARFITT:</p> <p>19 Q I do. Okay. What I'm talking about is</p> <p>20 if I called up Johns Hopkins and said, I have been</p> <p>21 diagnosed with ovarian cancer, I need to see a</p> <p>22 physician, would I be referred to the pulmonology</p> <p>23 department, your department, or would I be</p> <p>24 referred to a different department?</p> <p>25 MS. BROWN: Objection to the form.</p>	<p style="text-align: right;">Page 120</p> <p>1 hygienist?</p> <p>2 A No.</p> <p>3 Q Okay. Are you what's referred to as a</p> <p>4 mineralogist or a mineral scientist specialist?</p> <p>5 A Neither one.</p> <p>6 Q Are you a geologist?</p> <p>7 A No.</p> <p>8 Q Okay. Is it fair to say that you do not</p> <p>9 hold yourself out in the scientific and medical</p> <p>10 community as an expert with regard to testing</p> <p>11 standards of particulate matter, toxins or</p> <p>12 carcinogens?</p> <p>13 A I think that sounds right.</p> <p>14 Q And that would include testing of</p> <p>15 minerals -- or, excuse me, that would include</p> <p>16 testing of asbestos?</p> <p>17 MS. BROWN: Objection to the form.</p> <p>18 THE WITNESS: Correct.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q And that would include testing of talcum</p> <p>21 powder products?</p> <p>22 A That I -- I don't do that, is that</p> <p>23 right?</p> <p>24 Q Right.</p> <p>25 A Yeah, that's correct.</p>
<p style="text-align: right;">Page 119</p> <p>1 THE WITNESS: Different department,</p> <p>2 assuming it's literally for the care of the</p> <p>3 ovarian cancer.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay. Fair. Thank you.</p> <p>6 Have you ever researched the life</p> <p>7 expectancy of a woman who has ovarian cancer?</p> <p>8 A No.</p> <p>9 MS. BROWN: Objection to the form.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Are you a pathologist?</p> <p>12 A I am not.</p> <p>13 Q All right. And are you a radiologist?</p> <p>14 A I am not.</p> <p>15 Q Okay. Are you a mineralogist?</p> <p>16 A No.</p> <p>17 Q Are you a toxicologist?</p> <p>18 A No.</p> <p>19 Q Are you a pharmacologist?</p> <p>20 A No.</p> <p>21 Q Okay. Are you a regulatory expert?</p> <p>22 A I don't know what that means, but I</p> <p>23 don't -- I don't use those words to describe</p> <p>24 myself.</p> <p>25 Q Okay. Are you a certified industrial</p>	<p style="text-align: right;">Page 121</p> <p>1 Q All right. Let's talk a little bit</p> <p>2 about your publications and your research.</p> <p>3 Let me direct your attention to -- I</p> <p>4 believe this is Appendix C of your CV, which I</p> <p>5 believe is Exhibit 7.</p> <p>6 Do you have that in front of you?</p> <p>7 A I do.</p> <p>8 Q Okay. I understand, now that I have a</p> <p>9 CV that's dated June of 2017, and the CV I have,</p> <p>10 it says that you've published approximately 167</p> <p>11 publications in peer-reviewed literature.</p> <p>12 Is that correct or incorrect?</p> <p>13 A It was probably true as of June 2017.</p> <p>14 Q All right. So sitting here today in</p> <p>15 April of 2019, approximately how many publications</p> <p>16 in peer-reviewed journals have you published?</p> <p>17 A I think if you look on PubMed, you will</p> <p>18 see more than 200.</p> <p>19 Q Okay. Is it fair to say that you've</p> <p>20 published no papers or studies in the peer-</p> <p>21 reviewed literature about asbestos or asbestos-</p> <p>22 related diseases?</p> <p>23 A Correct.</p> <p>24 Well, can you ask that as two different</p> <p>25 questions?</p>

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<p>1 Q Sure.</p> <p>2 A I can help you just clarify what I --</p> <p>3 what I'm trying to answer.</p> <p>4 Q Please.</p> <p>5 A So nothing about asbestos, but if you --</p> <p>6 if you consider asbestos-related diseases to</p> <p>7 include lung cancer, for example, that there are</p> <p>8 publications that bear on lung cancer, and there's</p> <p>9 at least one article, maybe more, on interstitial</p> <p>10 lung diseases, and asbestosis would be an</p> <p>11 interstitial lung disease.</p> <p>12 Q Okay. Can you tell me what those</p> <p>13 articles are?</p> <p>14 A Let's see. Would the -- how do you want</p> <p>15 me to do it, like the number?</p> <p>16 Q If you give me the number, that would be</p> <p>17 fine.</p> <p>18 A Yeah. So number 5 has to do with lung</p> <p>19 cancer.</p> <p>20 Q Now, does that have to do with lung</p> <p>21 cancer and asbestos exposure?</p> <p>22 A No, not specifically.</p> <p>23 Q All right. So that has -- that is not</p> <p>24 lung cancer and asbestos.</p> <p>25 All right. Is there another one?</p>	<p>1 THE WITNESS: So that's a different</p> <p>2 question. So the answer to that is no.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q All right. Have you published any</p> <p>5 papers in the peer-reviewed literature on</p> <p>6 mesothelioma?</p> <p>7 A No.</p> <p>8 Q All right. So nowhere in the 200</p> <p>9 publications that you have prepared would I see</p> <p>10 the word "mesothelioma"?</p> <p>11 A I can't promise that you won't see that</p> <p>12 word in some paper, but there's not a paper whose</p> <p>13 primary topic is about mesothelioma.</p> <p>14 Q All right. Very good.</p> <p>15 Having reviewed your 200 or so</p> <p>16 publications, is it fair to say that there are no</p> <p>17 peer-reviewed publications regarding the subject</p> <p>18 matter of ovarian cancer?</p> <p>19 A That's correct.</p> <p>20 Q Is it fair to say that none of your</p> <p>21 peer-reviewed papers address a diagnosis of</p> <p>22 ovarian cancer?</p> <p>23 MS. BROWN: Objection. Form. I don't</p> <p>24 understand that.</p> <p>25 THE WITNESS: Well, I think -- I think</p>
Page 123	Page 125
<p>1 A Yeah, so if you look at number 6, this</p> <p>2 is, you know, a study about evaluating lung masses</p> <p>3 and large lymph nodes.</p> <p>4 Q Yes.</p> <p>5 A So that would include, you know, lung</p> <p>6 cancer in that as well.</p> <p>7 Q Does that include asbestos and lung</p> <p>8 cancer?</p> <p>9 A Not specifically.</p> <p>10 Q All right. Any others?</p> <p>11 A I would say any of the ones where you</p> <p>12 see the word "bronchoscopy," it has something to</p> <p>13 do with lung cancer for the most part, though not</p> <p>14 literally lung cancer and asbestos.</p> <p>15 So, for example, like 21, number 2,</p> <p>16 number 3, you know, all sort of have some bearing</p> <p>17 on at least the -- you know, the care or</p> <p>18 management of people with suspected lung cancer or</p> <p>19 who actually have lung cancer.</p> <p>20 Q Dr. Diette, my question is very specific</p> <p>21 to publications in the peer-reviewed journal that</p> <p>22 deal with the topic of asbestos or asbestos-</p> <p>23 related diseases like lung cancer where the word</p> <p>24 "asbestos" appears in your publication.</p> <p>25 MS. BROWN: Objection to the form.</p>	<p>1 the answer to the one before encompasses, you</p> <p>2 know, something else with the word "ovarian</p> <p>3 cancer" in the question.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay. All right. Have you published</p> <p>6 any peer-reviewed publications that talk about the</p> <p>7 causes of ovarian cancer?</p> <p>8 MS. BROWN: Objection.</p> <p>9 THE WITNESS: No.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Have you published any peer-reviewed</p> <p>12 papers that talk about risk factors for ovarian</p> <p>13 cancer?</p> <p>14 MS. BROWN: Same objection.</p> <p>15 THE WITNESS: No.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Have you published any publications in</p> <p>18 the peer-reviewed journal on risk factors for</p> <p>19 mesothelioma?</p> <p>20 A No.</p> <p>21 Q What causes mesothelioma?</p> <p>22 A A few things. You know, asbestos in</p> <p>23 sufficient dose can do it. Radiation can do it.</p> <p>24 There's some other minerals that aren't asbestos</p> <p>25 that are suspected to do it. It can arise on its</p>

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<p style="text-align: right;">Page 126</p> <p>1 own spontaneously. And, you know, there's</p> <p>2 thoughts of, at least in the peritoneum, about</p> <p>3 certain kinds of chronic inflammation that may</p> <p>4 lead to that as well.</p> <p>5 Q Okay. Can asbestos cause lung cancer?</p> <p>6 A Yes. In a sufficient dose.</p> <p>7 Q Okay. Is it fair to say that you have</p> <p>8 not published in the peer-reviewed literature any</p> <p>9 studies on talcum powder products as a causative</p> <p>10 factor for ovarian cancer?</p> <p>11 A That is correct.</p> <p>12 Q Is it fair to say that you have not</p> <p>13 published in the peer-reviewed journal any studies</p> <p>14 with regard to talcum powder products as a risk</p> <p>15 factor for ovarian cancer?</p> <p>16 A That's correct.</p> <p>17 Q Is it fair to say to say that there are</p> <p>18 no publications in your peer-reviewed literature</p> <p>19 on the subject of talcum -- of talc as a source of</p> <p>20 asbestos fibers?</p> <p>21 MS. BROWN: Objection. Counsel, I think</p> <p>22 you just misspoke. Do you mean on his CV?</p> <p>23 MS. PARFITT: I'm sorry? I did.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Is it fair to say --</p>	<p style="text-align: right;">Page 128</p> <p>1 A Right, are there -- no.</p> <p>2 Q Okay. I noted in your CV or in some of</p> <p>3 the readings that you are currently involved in</p> <p>4 some clinical trials.</p> <p>5 Did I -- did I get that correct?</p> <p>6 A I have been involved in trials.</p> <p>7 Q Something recent?</p> <p>8 A Oh, all the time.</p> <p>9 Q Okay. Are you currently involved in any</p> <p>10 clinical trial --</p> <p>11 A Yeah.</p> <p>12 Q -- trials?</p> <p>13 Okay. Do any of them deal with the</p> <p>14 subject of asbestos?</p> <p>15 A No.</p> <p>16 Q Do any of your trials or research deal</p> <p>17 with the subject of talcum powder products?</p> <p>18 A No.</p> <p>19 Q All right. Do you currently have</p> <p>20 ongoing any research work in the area of asbestos?</p> <p>21 MS. BROWN: Objection to the form.</p> <p>22 THE WITNESS: No.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Do you currently have ongoing in any of</p> <p>25 your research work on the topic of mesothelioma?</p>
<p style="text-align: right;">Page 127</p> <p>1 MS. PARFITT: Thank you.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Is it fair to say that there are no</p> <p>4 peer-reviewed publications in your CV that discuss</p> <p>5 the subject as -- of talc as a source of asbestos</p> <p>6 fibers?</p> <p>7 A Correct.</p> <p>8 Q Is it fair to say there are no</p> <p>9 publications in a peer-reviewed journal contained</p> <p>10 in your curriculum vitae regarding the association</p> <p>11 or relationship between talcum powder products and</p> <p>12 ovarian cancer?</p> <p>13 MS. BROWN: Objection to the form of the</p> <p>14 question.</p> <p>15 THE WITNESS: Correct.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Are there any publications in --</p> <p>18 peer-reviewed publications on your curriculum</p> <p>19 vitae regarding the association or relationship</p> <p>20 between asbestos and ovarian cancer?</p> <p>21 MS. BROWN: Objection. Asked and</p> <p>22 answered.</p> <p>23 THE WITNESS: You said are there any --</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Asbestos.</p>	<p style="text-align: right;">Page 129</p> <p>1 A No.</p> <p>2 Q Do you currently have any research work</p> <p>3 ongoing on the topic of talcum powder products?</p> <p>4 A No.</p> <p>5 Q Do you currently have any research in</p> <p>6 the works with regard to work on -- work on</p> <p>7 ovarian cancer?</p> <p>8 A No.</p> <p>9 MS. BROWN: Objection to the form.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Okay. Would it be fair to say that the</p> <p>12 only report that you have prepared on the topic of</p> <p>13 talcum powder products and ovarian cancer would be</p> <p>14 your litigation report --</p> <p>15 MS. BROWN: Object --</p> <p>16 BY MS. PARFITT:</p> <p>17 Q -- in the multidistrict litigation?</p> <p>18 MS. BROWN: Objection to the form,</p> <p>19 misstates his testimony.</p> <p>20 THE WITNESS: I doubt it's the only</p> <p>21 report. But I certainly did prepare a report for</p> <p>22 this.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Okay. How many reports have you</p> <p>25 prepared on the issue of talcum powder products</p>

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<p style="text-align: right;">Page 130</p> <p>1 and ovarian cancer?</p> <p>2 MS. BROWN: Objection to the form.</p> <p>3 Litigation?</p> <p>4 MS. PARFITT: Litigation reports.</p> <p>5 THE WITNESS: Like less than ten, and --</p> <p>6 and I may be getting the terminology wrong. I</p> <p>7 think there's like a couple of affidavits that I</p> <p>8 think to me are like a report. So I don't know --</p> <p>9 BY MS. PARFITT:</p> <p>10 Q That's a good clarification.</p> <p>11 MS. BROWN: Well, let him finish. Let</p> <p>12 him finish.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q I was trying to clarify for you, Doctor.</p> <p>15 MS. BROWN: Right, but just let him</p> <p>16 finish and then you can clarify.</p> <p>17 MS. PARFITT: Counsel, I will. Please.</p> <p>18 THE WITNESS: But -- but that's what I</p> <p>19 meant, so there's -- there's other things that</p> <p>20 I've sort of written in the litigation work that</p> <p>21 are other than just this report that we're looking</p> <p>22 at here today.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Okay. So your understanding of what you</p> <p>25 have prepared in written form on talcum powder</p>	<p style="text-align: right;">Page 132</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Okay. So the record is clear and I'm</p> <p>3 clear --</p> <p>4 A Yeah.</p> <p>5 Q -- the only report that you have</p> <p>6 prepared dealing with the -- your evaluation of</p> <p>7 the epidemiology on talcum powder products and</p> <p>8 ovarian cancer is the report that we have marked</p> <p>9 as exhibit -- I guess we haven't had it marked</p> <p>10 yet, but is the report that you filed in this</p> <p>11 case; is that right?</p> <p>12 MS. BROWN: Objection. Misstates his</p> <p>13 testimony.</p> <p>14 MS. MILLER: When you say "report," do</p> <p>15 you mean depositions?</p> <p>16 MS. PARFITT: Counsel, I -- I know --</p> <p>17 we'll get to it. You'll get a -- you'll get a</p> <p>18 question.</p> <p>19 MS. MILLER: It's not about us having a</p> <p>20 question. It's about you asking fair questions.</p> <p>21 MR. TISI: Well, it's not -- her job --</p> <p>22 I'm going to jump in here because --</p> <p>23 MS. PARFITT: Okay. Right.</p> <p>24 MR. TISI: -- now you're double teaming.</p> <p>25 I assume you have competent counsel defending this</p>
<p style="text-align: right;">Page 131</p> <p>1 products and ovarian cancer would be, one,</p> <p>2 affidavits. Correct?</p> <p>3 A Correct.</p> <p>4 Q And two, a legal expert report or more?</p> <p>5 MS. BROWN: Form.</p> <p>6 THE WITNESS: Correct.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Okay. Do you know whether or not you</p> <p>9 have prepared any legal expert reports like the</p> <p>10 one you prepared here in the MDL?</p> <p>11 MS. BROWN: Objection to the form.</p> <p>12 THE WITNESS: Well, on any topic?</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Affidavits -- no, on ovarian cancer and</p> <p>15 talcum powder products.</p> <p>16 A I don't think I --</p> <p>17 MS. BROWN: I object.</p> <p>18 THE WITNESS: I'm sorry.</p> <p>19 Yeah, I don't know if I've completed</p> <p>20 another -- another report, although I'm just</p> <p>21 trying to think if there was like -- like a case-</p> <p>22 specific report that might have had something in</p> <p>23 it. I mean not a report like this one, meaning</p> <p>24 where -- where the whole topic is just about</p> <p>25 the -- the epidemiology and so forth.</p>	<p style="text-align: right;">Page 133</p> <p>1 deposition. Honestly, you did this last week, and</p> <p>2 you've done it in every deposition, and you in</p> <p>3 particular, and you have a real problem with</p> <p>4 obstructing depositions. You need to stop.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Okay. Dr. Diette, I'll try and break it</p> <p>7 down, and I'm just trying to -- this isn't a trick</p> <p>8 question. So you let me know if you don't</p> <p>9 understand my question.</p> <p>10 MS. BROWN: And, Counsel, in all</p> <p>11 seriousness, in an effort to help, are you meaning</p> <p>12 to include or exclude the Ingham affidavit, which</p> <p>13 I think is the --</p> <p>14 MS. PARFITT: I haven't gotten to it. I</p> <p>15 really haven't gotten to it. That's -- that's --</p> <p>16 I'm hoping that the doctor knows what he -- what</p> <p>17 he's filed.</p> <p>18 Let's have marked as Plaintiffs' Exhibit</p> <p>19 No. 10.</p> <p>20 (Diette Exhibit No. 10 was marked</p> <p>21 for identification.)</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Okay. Dr. Diette, let me present you</p> <p>24 with an "Expert Report of Gregory Diette for</p> <p>25 General Causation Daubert Hearing." Okay.</p>

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<p>1 A That's this --</p> <p>2 Q Do you see that?</p> <p>3 A That's this one for here?</p> <p>4 Q Correct.</p> <p>5 A Yes.</p> <p>6 Q All right. Now, you've identified on</p> <p>7 the record that the report I have handed you,</p> <p>8 which is Exhibit No. 10, is a copy of your federal</p> <p>9 court expert report in the matter of -- dealing</p> <p>10 with the issues of talc and ovarian cancer,</p> <p>11 correct?</p> <p>12 A Exactly right.</p> <p>13 Q And in addition to that report, you have</p> <p>14 prepared some affidavits in the past also</p> <p>15 addressing the topic of talcum powder products and</p> <p>16 ovarian cancer, correct?</p> <p>17 A That's correct.</p> <p>18 Q Okay. Have you prepared any reports on</p> <p>19 talcum powder products and ovarian cancer outside</p> <p>20 of the legal context?</p> <p>21 MS. BROWN: Objection to the form.</p> <p>22 THE WITNESS: No.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Okay. And have you provided any other</p> <p>25 type of written report in a legal context, aside</p>	<p>1 BY MS. PARFITT:</p> <p>2 Q That's correct.</p> <p>3 A Oh, yeah, so then, no, nothing --</p> <p>4 nothing for which I've been disclosed.</p> <p>5 Q Okay. But I take it that you have been</p> <p>6 retained -- you're currently retained to work on</p> <p>7 some other cases other than talcum powder products</p> <p>8 and ovarian cancer, is that correct, by Johnson &</p> <p>9 Johnson?</p> <p>10 MS. BROWN: Counsel, I'm going to -- to</p> <p>11 the extent you're asking about consulting</p> <p>12 engagements, I'm going to instruct him not to</p> <p>13 answer.</p> <p>14 BY MS. PARFITT:</p> <p>15 Q No, I'm asking this: Are you an expert</p> <p>16 on behalf of Johnson & Johnson and asbestos and --</p> <p>17 and ovarian cancer cases?</p> <p>18 A So there's a subtlety there, right,</p> <p>19 because -- I mean you may call this an asbestos</p> <p>20 and ovarian cancer case. I think it's a talcum</p> <p>21 powder and ovarian cancer case.</p> <p>22 Q Okay.</p> <p>23 A There's nothing that's about asbestos</p> <p>24 separately from what we're talking about here.</p> <p>25 Q Fair enough. Have you been retained by</p>
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<p>1 from affidavits and the MDL report that you have</p> <p>2 in front of you?</p> <p>3 MS. BROWN: Form.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q On talcum powder products and ovarian</p> <p>6 cancer. I'm just trying to find out your world.</p> <p>7 A No, I understand. And I'm not sure if</p> <p>8 there could be like a work in progress. But</p> <p>9 you're talking about completed, completed like</p> <p>10 products like this, right?</p> <p>11 Q Correct.</p> <p>12 A I -- I can't think of another one.</p> <p>13 Q Okay. Do you have another report and/or</p> <p>14 affidavit in progress in the talcum powder</p> <p>15 products cases and ovarian cancer?</p> <p>16 MS. BROWN: Dr. Diette, I'm going to</p> <p>17 instruct you to the extent you're doing any work</p> <p>18 on this issue that is in a consulting nature and</p> <p>19 has not been disclosed, you should not disclose</p> <p>20 that here.</p> <p>21 I assume counsel is only asking for</p> <p>22 situations in which you have been disclosed as an</p> <p>23 expert, and with that, you can answer the</p> <p>24 question.</p> <p>25 THE WITNESS: Is that right?</p>	<p>1 Johnson & Johnson to testify as a legal expert in</p> <p>2 any talcum powder product cases and meso- --</p> <p>3 mesothelioma?</p> <p>4 A Yes.</p> <p>5 Q Okay. Are you currently an expert in</p> <p>6 any of those cases?</p> <p>7 A Yes.</p> <p>8 Q How many?</p> <p>9 MS. BROWN: And again, Doctor, to the</p> <p>10 extent you've been disclosed, you can answer the</p> <p>11 question.</p> <p>12 THE WITNESS: So I don't -- I don't know</p> <p>13 the count then. I would estimate ten, but I could</p> <p>14 be off by a couple.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Have you given depositions in those</p> <p>17 cases yet?</p> <p>18 A In some cases I have.</p> <p>19 Q Okay. Is this the first deposition that</p> <p>20 you have given in talcum powder products and</p> <p>21 ovarian cancer?</p> <p>22 MS. BROWN: Objection.</p> <p>23 THE WITNESS: I don't think so.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Okay. Did you give testimony in the</p>

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<p style="text-align: right;">Page 138</p> <p>1 Ingham case?</p> <p>2 A I did.</p> <p>3 Q Okay. Did you testify at trial at the</p> <p>4 Ingham case?</p> <p>5 A I did not.</p> <p>6 Q Okay. Is there any other case other</p> <p>7 than the Ingham case where you have given</p> <p>8 deposition in an ovarian cancer and a talcum</p> <p>9 powder case?</p> <p>10 A I think there's at least one other one.</p> <p>11 Q Okay. Do you remember the name of it?</p> <p>12 A I don't. I could look at my testimony</p> <p>13 list and see if I can figure it out.</p> <p>14 Q Okay. And we'll have that marked as</p> <p>15 well. Why don't we have that marked as Diette</p> <p>16 Exhibit -- it's part of your exhibit number --</p> <p>17 it's part of your report, but we'll have it marked</p> <p>18 as a separate exhibit.</p> <p>19 (Counsel conferring.)</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Let me show you what's -- we'll have</p> <p>22 marked as Exhibit No. 11.</p> <p>23 (Diette Exhibit No. 11 was marked</p> <p>24 for identification.)</p> <p>25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 140</p> <p>1 yes.</p> <p>2 Q Okay. The last date I have here is</p> <p>3 September 28, '18.</p> <p>4 A No. It should go further.</p> <p>5 MS. BROWN: We have another page,</p> <p>6 Counsel.</p> <p>7 MS. PARFITT: Okay.</p> <p>8 THE WITNESS: I think it's two-sided, so</p> <p>9 it's the back of that page.</p> <p>10 MS. PARFITT: Okay. Well --</p> <p>11 MS. BROWN: Do you want my copy?</p> <p>12 MS. PARFITT: That would be great. I</p> <p>13 appreciate that. I will give it right back to</p> <p>14 you.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. All right. So the last date is</p> <p>17 February 22nd, 2019; is that correct?</p> <p>18 A That is.</p> <p>19 Q All right. Are you able to circle for</p> <p>20 me which cases are cases in which you have been</p> <p>21 retained as an expert in the -- on the topic of</p> <p>22 talcum powder products and ovarian cancer?</p> <p>23 MS. BROWN: Objection to the form.</p> <p>24 You can answer to the extent you know,</p> <p>25 Doctor.</p>
<p style="text-align: right;">Page 139</p> <p>1 Q All right. Let me show you what's</p> <p>2 Exhibit 11.</p> <p>3 MS. PARFITT: We have a copy for</p> <p>4 counsel.</p> <p>5 MS. BROWN: Thank you.</p> <p>6 MR. ROSEN: I think there's --</p> <p>7 THE WITNESS: Oh, there's two.</p> <p>8 MS. PARFITT: Oh, okay, we'll take one</p> <p>9 back. Thank you. Okay. Very good.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Dr. Diette, does this represent an</p> <p>12 accurate list of cases in which you have been</p> <p>13 retained as an expert since I believe 2014?</p> <p>14 A It is.</p> <p>15 Q All right. Are there any additions to</p> <p>16 this list of cases --</p> <p>17 A I'm sorry.</p> <p>18 Q -- where you've given testimony?</p> <p>19 A I'm sorry. I think I -- I wasn't paying</p> <p>20 attention to your last question.</p> <p>21 Q That's all right.</p> <p>22 A Did you say is this a list of cases that</p> <p>23 I provided depositions?</p> <p>24 Q Expert testimony.</p> <p>25 A Expert testimony. Then the answer is</p>	<p style="text-align: right;">Page 141</p> <p>1 THE WITNESS: I actually don't. I'd</p> <p>2 have to look it up to figure out if I'm right that</p> <p>3 there is one on here, but I don't know -- and</p> <p>4 other than Ingham, right?</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Yes, sir.</p> <p>7 A Other than Ingham, yeah, so I -- I'm not</p> <p>8 sure. I can't tell.</p> <p>9 Q All right. Have you -- we talked about</p> <p>10 your peer-reviewed publications. Are any of your</p> <p>11 public -- peer-reviewed publications discussing</p> <p>12 cohort studies?</p> <p>13 MS. BROWN: Objection to the form.</p> <p>14 THE WITNESS: So some of them are cohort</p> <p>15 studies.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q But you have performed --</p> <p>18 MS. BROWN: Let him answer, please.</p> <p>19 MS. PARFITT: Sure.</p> <p>20 THE WITNESS: That I performed, yes.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q All right. So in your carrier as a</p> <p>23 medical doctor, you have published cohort studies?</p> <p>24 A I have.</p> <p>25 Q What have been the general topics of</p>

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<p style="text-align: right;">Page 142</p> <p>1 those cohort studies?</p> <p>2 A Generally speaking, things related to</p> <p>3 respiratory diseases and -- and things people</p> <p>4 inhale.</p> <p>5 Q All right. Have you published case-</p> <p>6 control studies?</p> <p>7 A I don't know. I can't think of one. It</p> <p>8 doesn't mean that there isn't one, but I'm -- I</p> <p>9 can't think of a case-control study.</p> <p>10 Q All right. Is it fair to say that none</p> <p>11 of the published cohort studies address the issue</p> <p>12 of talcum powder products and ovarian cancer?</p> <p>13 A Correct.</p> <p>14 Q And is it fair to say that none of the</p> <p>15 cohort studies that you published address the</p> <p>16 issue of talcum powder products and mesothelioma?</p> <p>17 A Correct.</p> <p>18 Q Is it fair to say that none of the</p> <p>19 cohort studies that you have published address the</p> <p>20 issue of asbestos and mesothelioma?</p> <p>21 A Correct.</p> <p>22 Q Is it fair to say that -- that the</p> <p>23 majority of your publications in your -- listed in</p> <p>24 your curriculum CV and those that you said you</p> <p>25 have published since 2017 deal primarily in the</p>	<p style="text-align: right;">Page 144</p> <p>1 MS. BROWN: Wait. Hold on. Is that a</p> <p>2 question?</p> <p>3 MS. PARFITT: Mm-hmm.</p> <p>4 MS. BROWN: I didn't understand that.</p> <p>5 If you understood it, you can answer.</p> <p>6 THE WITNESS: Well, the papers I was</p> <p>7 thinking about had to do with methods and</p> <p>8 quality -- quality assessment in terms of</p> <p>9 healthcare.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Okay.</p> <p>12 A I don't know if I've published anything</p> <p>13 on epi methods, meaning like, you know, the topic</p> <p>14 of a case-control study or --</p> <p>15 Q Right.</p> <p>16 A -- cohort studies, things of that sort.</p> <p>17 Q So it would be fair to say that you have</p> <p>18 not published in a peer-reviewed journal a paper</p> <p>19 on study designs, correct?</p> <p>20 MS. BROWN: Objection to the form.</p> <p>21 THE WITNESS: I would have to look back</p> <p>22 and see. I mean it's -- it's possible I've been</p> <p>23 involved in something that -- that -- I mean it's</p> <p>24 just hard to remember. It's 200 plus papers,</p> <p>25 so --</p>
<p style="text-align: right;">Page 143</p> <p>1 research interests of lung disease, COPD,</p> <p>2 asthma --</p> <p>3 MS. BROWN: Objection --</p> <p>4 BY MS. PARFITT:</p> <p>5 Q -- pulmonary medicine, lung diseases?</p> <p>6 MS. BROWN: Objection to the form.</p> <p>7 THE WITNESS: There's certainly plenty</p> <p>8 there. You know, I get different feedback from</p> <p>9 different people who look at my CV to tell whether</p> <p>10 or not it's, you know, all that or whether there's</p> <p>11 other things. I think people read into it what</p> <p>12 they -- what they see. Because there's -- you</p> <p>13 know, there's ICU research topics, there's</p> <p>14 procedure-related topics, there's radiology</p> <p>15 topics. I mean there's all -- all sorts of</p> <p>16 different things besides those.</p> <p>17 BY MS. PARFITT:</p> <p>18 Q Okay. Do you publish on methods and</p> <p>19 methodology?</p> <p>20 MS. BROWN: Form.</p> <p>21 THE WITNESS: So I think there's a</p> <p>22 couple of methods -- methods related papers.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Papers that deal primarily with</p> <p>25 epidemiological methodology?</p>	<p style="text-align: right;">Page 145</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Right. So nothing you can remember</p> <p>3 today.</p> <p>4 A Correct.</p> <p>5 Q Okay. And have you published on the</p> <p>6 Bradford Hill factors?</p> <p>7 MS. BROWN: Form.</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: So I've not written a</p> <p>10 paper about Bradford Hill.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q All right. In any of the 200 papers</p> <p>13 that you have published in a peer-reviewed</p> <p>14 journal, do you set forth in those papers the</p> <p>15 Bradford Hill framework?</p> <p>16 MS. BROWN: Objection to the form of the</p> <p>17 question.</p> <p>18 THE WITNESS: You couldn't do it.</p> <p>19 Right. I mean, it's -- the papers that I write</p> <p>20 are primary research papers, and that framework</p> <p>21 doesn't belong in those papers, but we articulate</p> <p>22 the -- the issues that are -- that are relevant</p> <p>23 for a Bradford Hill analysis.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Okay. Well, in this expert report that</p>

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<p style="text-align: right;">Page 146</p> <p>1 you did file in the federal court, you stated</p> <p>2 specifically that you followed the Bradford Hill</p> <p>3 framework. Do you recall saying that?</p> <p>4 A I -- I do. There was more to it, but it</p> <p>5 included that.</p> <p>6 Q Okay. So what I'm asking you, in any of</p> <p>7 the papers, whether they be cohort study, case</p> <p>8 control, other research and scientific</p> <p>9 publications that you've listed on your curriculum</p> <p>10 vitae, have you stated in those papers that you</p> <p>11 are following or are guided by the Bradford Hill</p> <p>12 framework?</p> <p>13 MS. BROWN: Objection. He just answered</p> <p>14 that.</p> <p>15 THE WITNESS: Yeah, it's sort of baked</p> <p>16 into what we do. So it's like in -- I mean the</p> <p>17 answer is no, generally, but -- but we include</p> <p>18 things in a way that they fit with what Bradford</p> <p>19 Hill considerations are. But there's not one that</p> <p>20 was called like the Bradford Hill approach or</p> <p>21 something.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Okay. And by --</p> <p>24 MS. BROWN: Let him finish.</p> <p>25 Were you finished, Doctor?</p>	<p style="text-align: right;">Page 148</p> <p>1 different than what you asked? Because I'm</p> <p>2 just --</p> <p>3 BY MS. PARFITT:</p> <p>4 Q It is.</p> <p>5 This would be some original research</p> <p>6 that you might be -- got a funding or a grant or</p> <p>7 something.</p> <p>8 A I see. Nothing like that.</p> <p>9 Q Okay. Have you received any funds --</p> <p>10 any funding or any grants to study mesothelioma?</p> <p>11 A No.</p> <p>12 Q Have you received any funding or grants</p> <p>13 to study asbestos?</p> <p>14 A No.</p> <p>15 Q Have you received any funding or grants</p> <p>16 to study talcum powder products and their</p> <p>17 association with ovarian cancer?</p> <p>18 MS. BROWN: Objection to the form.</p> <p>19 THE WITNESS: No.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Have you ever published in peer-reviewed</p> <p>22 literature a causation analysis or a review</p> <p>23 article asking whether an exposure causes a</p> <p>24 disease?</p> <p>25 MS. BROWN: Objection to the form of the</p>
<p style="text-align: right;">Page 147</p> <p>1 THE WITNESS: I'm okay. Thank you.</p> <p>2 MS. PARFITT: Thank you.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q Assume I did a search of the word</p> <p>5 "Bradford Hill" in the 167 papers that you have</p> <p>6 published in the peer-reviewed journal, would it</p> <p>7 surprise you if those words did not appear?</p> <p>8 MS. BROWN: Objection to the form.</p> <p>9 THE WITNESS: It wouldn't surprise me,</p> <p>10 but I -- I don't know that it's not there</p> <p>11 somewhere. And I would search more broadly than</p> <p>12 just those 167. I would look at the more recent</p> <p>13 ones too. I mean I can't say that it's not there,</p> <p>14 but there's not a paper about Bradford Hill.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. Have you been involved in any</p> <p>17 original research on asbestos in general?</p> <p>18 MS. BROWN: Objection to the form.</p> <p>19 THE WITNESS: I have not.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Have you -- have you conducted any</p> <p>22 original research on ovarian cancer?</p> <p>23 MS. BROWN: Objection to the form, asked</p> <p>24 and answered.</p> <p>25 THE WITNESS: I guess, I mean -- is it</p>	<p style="text-align: right;">Page 149</p> <p>1 question.</p> <p>2 THE WITNESS: I don't know. I would</p> <p>3 have to look back over. I don't -- like I don't</p> <p>4 know if I would use those words "causation</p> <p>5 analysis," but we certainly write -- did you say</p> <p>6 review article?</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Yes.</p> <p>9 A So I don't write many review articles.</p> <p>10 They're really -- they're really low quality</p> <p>11 academic products for the most part, and so I try</p> <p>12 to focus more on original research.</p> <p>13 Q All right. Well, same question applied</p> <p>14 to original research.</p> <p>15 MS. BROWN: Objection to the form.</p> <p>16 THE WITNESS: Well, it wouldn't be -- I</p> <p>17 mean that wouldn't be an original research</p> <p>18 article.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q Okay. Have you ever performed any</p> <p>21 research on the environmental impacts of talcum</p> <p>22 powder products and ovarian cancer?</p> <p>23 MS. BROWN: Objection to the form,</p> <p>24 vague.</p> <p>25 THE WITNESS: No.</p>

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<p style="text-align: right;">Page 150</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Environmental impacts of diseases is</p> <p>3 something -- is a topic that you are interesting</p> <p>4 in, correct?</p> <p>5 A I am.</p> <p>6 Q You've studied the impact of</p> <p>7 environmental effects on lung diseases, correct?</p> <p>8 A I have.</p> <p>9 Q In fact, that's something you continue</p> <p>10 to be interested in, correct?</p> <p>11 A I am.</p> <p>12 Q But you've not studied any environmental</p> <p>13 impacts on ovarian cancer, correct?</p> <p>14 A Correct.</p> <p>15 MS. BROWN: Asked and answered.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Would it be fair to say that prior to</p> <p>18 being retained by Johnson & Johnson sometime in</p> <p>19 2017, you had done no research on the issue of</p> <p>20 talcum powder products and ovarian cancer?</p> <p>21 MS. BROWN: Objection to the form,</p> <p>22 misstates his testimony.</p> <p>23 THE WITNESS: I think it's the same as</p> <p>24 before. Right. I mean you went through each --</p> <p>25 each item, and my answer was no.</p>	<p style="text-align: right;">Page 152</p> <p>1 Q And to give you some -- a reference,</p> <p>2 we'll spend a little time on that before we get</p> <p>3 into your report. All right? Fair?</p> <p>4 A Sounds good.</p> <p>5 Q Okay. What is Medical Science</p> <p>6 Affiliates?</p> <p>7 A I think they -- they call themselves an</p> <p>8 environmental consulting company.</p> <p>9 Q How long have you been involved with</p> <p>10 Medical Science Affiliates?</p> <p>11 MS. BROWN: Form.</p> <p>12 THE WITNESS: So involved, I guess we'll</p> <p>13 have to sort, but I -- I've known about them and</p> <p>14 done some work with them for about ten years.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. And I too want to sort, so let me</p> <p>17 ask you this: When were you first introduced to</p> <p>18 Medical Science Affiliates?</p> <p>19 A Well, I guess if it's ten years, it</p> <p>20 would have been about ten years ago.</p> <p>21 Q And what were -- how did it come about</p> <p>22 that you learned of a group called Medical Science</p> <p>23 Affiliates?</p> <p>24 A There was a woman who worked there</p> <p>25 then -- I don't remember what her name is, she's</p>
<p style="text-align: right;">Page 151</p> <p>1 BY MS. PARFITT:</p> <p>2 Q So it was not until you were retained by</p> <p>3 Johnson & Johnson that you conducted any research</p> <p>4 on the topic of ovarian cancer and talcum powder</p> <p>5 products, correct?</p> <p>6 MS. BROWN: Objection to the form,</p> <p>7 misstates his testimony.</p> <p>8 THE WITNESS: That is right.</p> <p>9 MS. PARFITT: Okay. And is now a good</p> <p>10 time for a bio break or is it --</p> <p>11 MS. PARFITT: Sure.</p> <p>12 THE WITNESS: If you're in the middle of</p> <p>13 something, I --</p> <p>14 MS. PARFITT: No, no, this is fine.</p> <p>15 We'll just move into another area quickly, yeah.</p> <p>16 THE VIDEOGRAPHER: The time is</p> <p>17 11:14 a.m., and we're going off the record.</p> <p>18 (Recess.)</p> <p>19 THE VIDEOGRAPHER: The time is</p> <p>20 11:24 a.m., and we are back on the record.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q All right. Dr. Diette, I want to talk</p> <p>23 for a moment about Medical Science Affiliates.</p> <p>24 All right?</p> <p>25 A Okay.</p>	<p style="text-align: right;">Page 153</p> <p>1 not there anymore -- and she knew a colleague of</p> <p>2 mine, and they were I think at the time looking</p> <p>3 for somebody to take on an epidemiology project, a</p> <p>4 review. And so he -- he sent around like a note</p> <p>5 or talked to us, I don't remember how he did it,</p> <p>6 but to see if anybody was interested in -- in</p> <p>7 doing an epidemiology project.</p> <p>8 Q Who was that colleague?</p> <p>9 A I think it was Hank Fessler, but I could</p> <p>10 be wrong. That's a while ago.</p> <p>11 Q And what is his position within the</p> <p>12 university?</p> <p>13 A He works in pulmonary.</p> <p>14 Q Okay. So you were -- you were then</p> <p>15 engaged by Medical Science Affiliates to do an</p> <p>16 epidemiological report for them?</p> <p>17 MS. BROWN: Objection. Misstates</p> <p>18 testimony.</p> <p>19 THE WITNESS: I don't know about</p> <p>20 engaged. I mean my -- my relationship is as an</p> <p>21 independent contractor. So it's like -- it's not</p> <p>22 like I have an agreement to do anything with them</p> <p>23 or for them. But that's -- that's the place</p> <p>24 where, you know, they organize the materials for</p> <p>25 me to look over and to -- and to do the</p>

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<p style="text-align: right;">Page 154</p> <p>1 epidemiological review. 2 BY MS. PARFITT: 3 Q Okay. Your counsel has objected, as you 4 heard, to me obtaining a copy of your agreement, 5 so I'm going to have to ask you a few more 6 questions about this. 7 What is your arrangement with Medical 8 Science Affiliates? Independent contractor? 9 A That's exactly right. 10 MS. BROWN: He just said it. 11 MS. PARFITT: Okay. I understand. You 12 can take your own deposition, Counsel. It's going 13 to show up on the record too, you're rubbing your 14 head. 15 BY MS. PARFITT: 16 Q Medical Science, you have an independent 17 contract relationship, to do what? 18 A I think what it establishes is that I 19 can use their administrative services as kind of 20 like an outside office for me to do work. 21 Q Okay. So that's one role, they're an 22 outside office. You mentioned, though, that they 23 contracted you to also write an epidemiology 24 report. Correct? 25 A It's --</p>	<p style="text-align: right;">Page 156</p> <p>1 Q More 50? 2 A At least 50. 3 Q Okay. And what has been the topic of 4 those reports that you have prepared for Medical 5 Science Affiliates' clients? 6 MS. BROWN: And I'm going to jump in 7 here. To the extent that those projects are 8 governed by confidentiality agreements, I would 9 ask Dr. Diette that you only disclose that which 10 has been disclosed publicly, for example, in court 11 or at a deposition. 12 MS. PARFITT: Please stop coaching the 13 witness. 14 BY MS. PARFITT: 15 Q Can you answer? 16 MS. BROWN: We're trying to protect 17 confidentiality. 18 MS. PARFITT: I get -- 19 MS. BROWN: I'm instructing him on 20 privilege. 21 MS. PARFITT: That's fine. I 22 understood. He can talk now. 23 THE WITNESS: So I would say that most 24 of the work is in the context of what Ms. Brown 25 said, which is that it wasn't for me to share with</p>
<p style="text-align: right;">Page 155</p> <p>1 MS. BROWN: Objection to the form. 2 THE WITNESS: It's incorrect. 3 BY MS. PARFITT: 4 Q Okay. Straighten it out for me. 5 A Well, they didn't contract me to do 6 anything. They asked if I was interested in doing 7 this epidemiologic project for a client that they 8 knew of. 9 Q Okay. That helps me. 10 So Medical Science Affiliates reached 11 out -- requested that you do an epidemiological 12 report for one of their clients. 13 A Exactly right. 14 Q Okay. Over the course of ten years that 15 you've been affiliated as an independent 16 contractor with Medical Science Affiliates, how 17 many times have you prepared a report for one of 18 Medical Science Affiliates' clients? 19 A I don't know. 20 Q More than ten? 21 A Sure. 22 Q More than a hundred? 23 A A hundred would be pushing it. So 24 something in the tens, I would say. But not ten. 25 I mean something higher up in --</p>	<p style="text-align: right;">Page 157</p> <p>1 other people. 2 BY MS. PARFITT: 3 Q All right. Is J&J a client of Medical 4 Science Affiliates? 5 A I don't know what their relationship is, 6 like I don't know if you would call them a client 7 or not. 8 Q Okay. Does Medical Science Affiliates 9 do some work for Johnson & Johnson? 10 MS. BROWN: Objection. Speculation. 11 THE WITNESS: So I can tell you about 12 what they do for me with regard to Johnson & 13 Johnson. I don't know about anything else. 14 BY MS. PARFITT: 15 Q All right. Tell me what you know. 16 A Well, like, for example, like in the 17 cases that we've discussed that involve Johnson & 18 Johnson, they've provided a service by collecting 19 the materials, right. So, for example, like when 20 you see that list of materials that -- that I 21 provided that I reviewed, they will collect those 22 and -- and organize them for me. 23 If there's a need to have a meeting or a 24 phone call, they'll help to set that up, right, so 25 that -- so, for example, for the deposition today,</p>

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<p style="text-align: right;">Page 158</p> <p>1 they were able to help sort my -- through my 2 schedule, you know, with me, and figure out a day 3 or days, I don't remember what we offered, things 4 of that sort. They'll prepare invoices on my 5 behalf. They'll help edit a report. You know, 6 administrative type things. 7 Q Okay. Let's break that down a little 8 bit. 9 Is it your understanding that Medical 10 Science Affiliates bills Johnson & Johnson -- 11 MS. BROWN: Object -- 12 BY MS. PARFITT: 13 Q -- and invoices them for work? 14 MS. BROWN: Objection to the form, calls 15 for speculation. 16 BY MS. PARFITT: 17 Q If you know. 18 A I don't know where the bill goes because 19 I don't know if it goes to the law firm. Like if 20 it matters to you whether it's directly to Johnson 21 & Johnson or -- I mean I can only guess that, you 22 know, the law firm is not going to pay the bill 23 out of their own pocket. They're probably going 24 to then invoice Johnson & Johnson, but I don't 25 know whether the bill goes directly to Johnson &</p>	<p style="text-align: right;">Page 160</p> <p>1 you said, which is that they billed somebody else 2 for the work that they did. 3 BY MS. PARFITT: 4 Q Do you know who that somebody else is? 5 And I want to remind you you're under oath, 6 Dr. Diette. 7 MS. BROWN: What -- 8 THE WITNESS: What's -- 9 MS. BROWN: Whoa, whoa, whoa. I'm 10 objecting to the implication there. Dr. Diette 11 has done nothing but testify truthfully today. 12 MS. PARFITT: Counsel, objection, form. 13 I'm telling you. 14 BY MS. PARFITT: 15 Q Please go on, Dr. Diette. 16 MS. BROWN: No, but what you just said 17 is inappropriate -- 18 MS. PARFITT: It was not -- 19 MS. BROWN: -- and it violates both the 20 federal rules -- 21 MS. PARFITT: -- violative of anything, 22 Counsel. 23 MS. BROWN: -- as well as deposition 24 protocol. He of course is testifying under oath, 25 and if you're suggesting something otherwise,</p>
<p style="text-align: right;">Page 159</p> <p>1 Johnson or whether it goes to the law firm. 2 Q All right. 3 MS. BROWN: And, Doctor, counsel doesn't 4 want you to guess, so just answer the question the 5 best -- 6 BY MS. PARFITT: 7 Q Dr. Diette, if they -- Medical Science 8 Affiliates collects material for you -- as you say 9 they did, correct? 10 A That's correct. 11 Q -- do they bill you or do they bill 12 someone else? 13 MS. BROWN: Objection to the form. 14 THE WITNESS: They bill someone else. 15 BY MS. PARFITT: 16 Q Okay. So when you testified that J&J -- 17 excuse me, when you testified that you had 18 assistance with regard to the preparation of some 19 of the materials that accompany your report, that 20 was work that you contracted with Medical Service 21 Affiliates to do, and they didn't bill you, they 22 billed somebody else, correct? 23 MS. BROWN: Objection to the form. 24 THE WITNESS: I don't know if 25 "contracted" is right, but -- but they did what</p>	<p style="text-align: right;">Page 161</p> <p>1 that's wildly inappropriate. 2 MS. PARFITT: Counsel, let the Court 3 decide if it's -- I think the Court might decide 4 that your objections and your manner today are 5 wildly inappropriate. 6 BY MS. PARFITT: 7 Q So, Dr. Diette, so we can move forward, 8 do you remember the question? 9 A I remember it, but I think I already 10 answered it. It's -- I don't have a better answer 11 than what I gave you before. 12 Q You don't know who Medical Science 13 billed for the services they rendered to you? 14 A Well, let's look at the invoice if we 15 want to. If it's on the top of that, then I 16 might -- 17 Q It's been blacked out, Dr. Diette. 18 A So it's either a law firm or it's 19 Johnson & Johnson. I don't know whether it's one 20 or the other. 21 MS. BROWN: Counsel, you're 22 misrepresenting the documents. It's very clear 23 who they sent the bill to on the face of the 24 invoice, and it has not been redacted for 25 work-product privilege.</p>

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<p style="text-align: right;">Page 162</p> <p>1 BY MS. PARFITT:</p> <p>2 Q What I want to understand, for purpose</p> <p>3 of the expert report you prepared in this</p> <p>4 litigation, I want you to tell me, if you will,</p> <p>5 every service that Medical Science Affiliates</p> <p>6 performed for you.</p> <p>7 A I don't think I can give you a full</p> <p>8 list. I think that the -- go ahead.</p> <p>9 Q No, no, please, go ahead.</p> <p>10 A All right. So I think the category of</p> <p>11 things that I told you about before are the kinds</p> <p>12 of things that they -- that they did in this case.</p> <p>13 I don't know if I mentioned like arranging like a</p> <p>14 phone call. Like if I was going to have a phone</p> <p>15 call, they would arrange that. Help with -- I</p> <p>16 already talked about editing -- editing reports</p> <p>17 and -- I can't think of another service they did,</p> <p>18 but that's what I can think of right now.</p> <p>19 Q Okay. Did Medical Science Affiliates</p> <p>20 research the scientific literature for you in</p> <p>21 preparation for some of the information contained</p> <p>22 in your expert report?</p> <p>23 A I don't -- I don't think they did any of</p> <p>24 that. I mean, they've -- they've done searches in</p> <p>25 the past on other -- other topics, but I don't</p>	<p style="text-align: right;">Page 164</p> <p>1 something else with the papers?</p> <p>2 Q I'll break it down. Did they do a</p> <p>3 literature search for you?</p> <p>4 A Yeah, and that's what I don't remember.</p> <p>5 So I'm just saying that they've done that at my</p> <p>6 request in the past. But not -- not too much. I</p> <p>7 mean it's actually not that helpful, because I --</p> <p>8 I find it easier to do it myself.</p> <p>9 Q Whether it was helpful or not, my</p> <p>10 question is, did Medical Science Affiliates do any</p> <p>11 literature research for you in -- on the topic of</p> <p>12 talcum powder products and ovarian cancer?</p> <p>13 A I can't give you a better answer. I</p> <p>14 mean I -- I think it sounds to me like you keep</p> <p>15 asking the same thing, and it -- my answer is I'm</p> <p>16 not -- I'm not sure. Like they may have gathered</p> <p>17 a couple of papers, I don't remember if they did</p> <p>18 or not. They certainly didn't do the search, like</p> <p>19 I didn't commission anybody to do like -- like the</p> <p>20 search.</p> <p>21 Q Okay. And how would they deliver that</p> <p>22 information to you? Do they e-mail it to you? Do</p> <p>23 they send it to you? What happens?</p> <p>24 A It depends upon how I ask. So it can</p> <p>25 come as a binder, like the binder you have in</p>
<p style="text-align: right;">Page 163</p> <p>1 think they did any for this.</p> <p>2 Q All right. So it's your testimony that</p> <p>3 in the talcum powder/ovarian cancer case, they did</p> <p>4 not do any research of the peer-reviewed</p> <p>5 literature; is that correct?</p> <p>6 A Well, let me be clear, when you talk</p> <p>7 about talcum powder and ovarian cancer -- because</p> <p>8 I have to think back with each -- you know, each</p> <p>9 case or whatever, but we're talking about this</p> <p>10 particular matter as you're asking these questions</p> <p>11 or --</p> <p>12 Q Well, that's a -- that's a great point.</p> <p>13 You got involved in talcum powder and ovarian</p> <p>14 cancer cases sometime in 2017. That's your</p> <p>15 testimony.</p> <p>16 A It is.</p> <p>17 Q All right. So at that point in time</p> <p>18 when you became engaged to work on talcum powder</p> <p>19 products and ovarian cancer, what I'm interested</p> <p>20 in knowing is whether or not, whether it was for</p> <p>21 this report, another report, has Medical Science</p> <p>22 Affiliates done any research work of the</p> <p>23 literature on this topic?</p> <p>24 A And by "research work," does that -- do</p> <p>25 you mean like finding papers or does it mean doing</p>	<p style="text-align: right;">Page 165</p> <p>1 front of you, it could like that, and be hard</p> <p>2 copies. It could be through, you know, an</p> <p>3 electronic mechanism, if there were something to</p> <p>4 share that way.</p> <p>5 Q All right. Did Medical Science</p> <p>6 Affiliates summarize any of those depositions that</p> <p>7 you have listed in your report?</p> <p>8 A I don't -- do I have -- I don't think --</p> <p>9 do I have deposition summaries?</p> <p>10 Q No.</p> <p>11 A Oh, then no.</p> <p>12 Q You have depositions.</p> <p>13 A Then the answer is no.</p> <p>14 Q Okay. Now, what you've provided me are</p> <p>15 reports and depositions of various experts either</p> <p>16 for Johnson & Johnson or for the plaintiff that</p> <p>17 you've indicated you've -- you've put them on your</p> <p>18 reliance list.</p> <p>19 And what I'm questioning is whether or</p> <p>20 not you've had any summaries done of those reports</p> <p>21 by Medical Science Affiliates.</p> <p>22 A No.</p> <p>23 Q Okay. Have they done any summaries of</p> <p>24 any type of information for you in the talcum</p> <p>25 powder products and ovarian cancer?</p>

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<p style="text-align: right;">Page 166</p> <p>1 MS. BROWN: And, Counsel, here I'm going 2 to interject, and to the extent your question -- 3 MS. PARFITT: Objection. Form. 4 MS. BROWN: -- seeks to -- I'm 5 instructing on privilege, which I'm allowed to do 6 under the federal rules and under the -- 7 MS. PARFITT: If it's a privilege 8 issue -- 9 MS. BROWN: -- let me do that. 10 MS. PARFITT: -- it's certainly fine. 11 MS. BROWN: Thanks. So my instruction 12 here will be that, Doctor, you are not under the 13 work-product privilege to disclose any 14 correspondence you've had with MSA, unless it is 15 something on which you rely for your opinions 16 here, and then of course, counsel is entitled to 17 have that information. 18 BY MS. PARFITT: 19 Q With that understanding, how do you 20 answer the question? 21 A Can you say it again because I think I 22 lost it? 23 Q Sure. Let me just have it read back to 24 you here. 25 Has Medical Science Affiliates done any</p>	<p style="text-align: right;">Page 168</p> <p>1 Q Did you use for purposes of your expert 2 report any of the summaries that were -- that were 3 conducted by Medical Science Affiliates that you 4 just spoke about? 5 A See, this is where I -- I don't know if 6 you're trying to confuse me or what, but -- 7 Q No, I'm not. 8 A Okay. So I just want to be clear, 9 because there aren't any summaries for this, 10 right. 11 Q Okay. 12 A So -- and that's why I keep trying to -- 13 I just -- because there's a different answer for 14 what -- what people have done in other matters and 15 what they've done in this matter. There aren't 16 any summaries that I'm aware of to -- to look at. 17 Q All right. Did Medical Science 18 Affiliates help you write your expert report? 19 MS. BROWN: Objection to the form of the 20 question. 21 THE WITNESS: You know, "write" is a -- 22 is a word that can mean a lot of things. They 23 helped me to -- to shape it, like to create the -- 24 the format for it and like edit out typos and 25 things of that sort.</p>
<p style="text-align: right;">Page 167</p> <p>1 summaries of any type of information for you -- or 2 provided any information for you on the talcum 3 powder products and ovarian cancer cases? 4 MS. BROWN: Same instruction. If you're 5 relying on anything they've done, of course, 6 please answer the question. 7 THE WITNESS: So if we're talking about 8 cases -- because that's why I clarified before, 9 we're not talking about this matter. We're 10 talking about ever in any -- in any case? 11 BY MS. PARFITT: 12 Q Ovarian cancer and talcum powder 13 products. 14 A Oh, yeah. No, I understand the words. 15 I'm just trying to make sure whether we're talking 16 about like this -- this matter that we're talking 17 about only or -- or beyond that. 18 Q Has -- has -- beyond that. 19 A So I'm going to say probably they have. 20 That if there are cases where there were like 21 medical records, for example, although I don't 22 think I've gotten any medical records, but they 23 would have provided a summary. If there were 24 deposition transcripts in those other cases, they 25 might well have -- have done that.</p>	<p style="text-align: right;">Page 169</p> <p>1 BY MS. PARFITT: 2 Q Okay. Well, that has -- it means a lot 3 of things as well. So let me ask you -- 4 MS. BROWN: Counsel, just ask the 5 question. 6 MS. PARFITT: Counsel, I'm -- please. 7 MS. BROWN: You can't editorialize like 8 that. It's a question and an answer. 9 BY MS. PARFITT: 10 Q Dr. Diette, what I would like to ask you 11 is, when you say they helped shape your report, 12 what do you mean they helped shape your report? 13 MS. BROWN: Objection. 14 THE WITNESS: What I just said -- I mean 15 what I said after -- after that before. 16 BY MS. PARFITT: 17 Q Is every word in your expert report that 18 you have there in front of you a word that you put 19 in it? 20 MS. BROWN: Objection to the form. 21 THE WITNESS: Well, I don't know. I 22 mean, there's -- there's quotes from people, 23 right, so that those aren't my words, for example. 24 BY MS. PARFITT: 25 Q Well, you know, I'm glad you brought</p>

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<p>1 that up. That's a good question.</p> <p>2 A Yeah.</p> <p>3 Q Are the opinions and the writings</p> <p>4 contained in that report words that you selected?</p> <p>5 A Oh, for sure. I mean like the opinions</p> <p>6 and my -- my summaries of things and -- is that</p> <p>7 what we're talking about?</p> <p>8 Q No. No.</p> <p>9 A We're not? All right.</p> <p>10 Q The report is about -- let's see how</p> <p>11 many pages -- it's about 51 pages long, and the</p> <p>12 question I have, with the exception of quotes from</p> <p>13 other people, Dr. Diette, is every word in this</p> <p>14 report a word you chose to put in the report?</p> <p>15 MS. BROWN: Objection to the form.</p> <p>16 THE WITNESS: For sure, yes. Although</p> <p>17 like some of the words, for example, I think might</p> <p>18 come from one of those affidavits that we were</p> <p>19 talking about, right. So it may be like, you</p> <p>20 know, words that I created in a different context</p> <p>21 and then pulled into this.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Okay. Well, then when you say "Medical</p> <p>24 Science Affiliates helped shape," I'm trying to</p> <p>25 get an understanding, what do you mean "shape"?</p>	<p>1 footnotes, like the information that comes from it</p> <p>2 was information that I pulled from the --</p> <p>3 Q Not my question. Who prepared the</p> <p>4 actual footnotes that appear at the bottom of your</p> <p>5 expert report of 58 -- or, excuse me, 51 pages?</p> <p>6 A So like actually put like -- like 110</p> <p>7 and then put like "Siemiatycki dep, 149"?</p> <p>8 Q Or how about put "226, Singh depo, don't</p> <p>9 consistently reduce," and there's a summary, I</p> <p>10 mean who provided that information, what staff?</p> <p>11 MS. BROWN: Objection to the form.</p> <p>12 Misstates his testimony about how the report was</p> <p>13 prepared.</p> <p>14 THE WITNESS: I'm sorry. We're looking</p> <p>15 at number 226.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q By way of example, Dr. Diette.</p> <p>18 A No, no, I'm just -- I'm just trying to</p> <p>19 help because an example helps.</p> <p>20 So I don't know. I mean some -- some</p> <p>21 staff person put that particular -- literally that</p> <p>22 segment in, but like it came from me identifying</p> <p>23 that NSAIDS don't consistently reduce the risk of</p> <p>24 ovarian cancer and wanting to link it there to my</p> <p>25 statement.</p>
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<p>1 A It would look like a disaster if I did</p> <p>2 this myself. So the fact that there are headings,</p> <p>3 that, you know, things don't spill over from one</p> <p>4 page to another. I don't remember if there's a</p> <p>5 table in here, but to not have the table split</p> <p>6 across, to have, you know, references look okay.</p> <p>7 That I'm not good at. So the fact that this, in</p> <p>8 my view, looks like a professional product, that's</p> <p>9 what they -- that's what they've done for me is to</p> <p>10 make it look like that.</p> <p>11 Q Okay. There are multiple footnotes in</p> <p>12 your report to testimony of various experts that</p> <p>13 were retained by the plaintiff.</p> <p>14 A Yeah.</p> <p>15 Q Who prepared those footnotes?</p> <p>16 MS. BROWN: Objection to the form.</p> <p>17 THE WITNESS: Staff somewhere, but --</p> <p>18 BY MS. PARFITT:</p> <p>19 Q I'm sorry.</p> <p>20 A Staff.</p> <p>21 Q Staff?</p> <p>22 A Yes.</p> <p>23 Q What staff?</p> <p>24 A I don't know which staff did it, but I</p> <p>25 mean like the -- if you say who prepared the</p>	<p>1 Q Who's the staff? Staff for MSA?</p> <p>2 A It could be MSA; it could be the law</p> <p>3 firm. I'm not sure which.</p> <p>4 Q Did you dictate to MSA or anyone else</p> <p>5 portions of your expert report, and someone else</p> <p>6 then did the recordation?</p> <p>7 A Somebody else did the --</p> <p>8 Q Did the -- did --</p> <p>9 A The --</p> <p>10 Q Did you dictate any portions of your</p> <p>11 report to anyone?</p> <p>12 A I don't -- I don't do that.</p> <p>13 Q You don't dictate. Okay.</p> <p>14 A No.</p> <p>15 Q Did you spend time on the phone with</p> <p>16 anyone at MSA and discuss what your -- your report</p> <p>17 should look like?</p> <p>18 MS. BROWN: And again, I'm going to</p> <p>19 instruct on work product, that you not reveal the</p> <p>20 substance of any discussions you had regarding</p> <p>21 drafts of this report. Whether or not there was a</p> <p>22 conversation is an appropriate question to answer.</p> <p>23 THE WITNESS: Sure.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q You did?</p>

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<p style="text-align: right;">Page 174</p> <p>1 A Yes.</p> <p>2 Q So you had a conversation --</p> <p>3 A Yes.</p> <p>4 Q -- about the substance of your report,</p> <p>5 correct?</p> <p>6 MS. BROWN: Objection to the form.</p> <p>7 THE WITNESS: Oh, no, you just -- you</p> <p>8 said something else before that. What was the</p> <p>9 question before?</p> <p>10 MS. BROWN: Discuss what your report</p> <p>11 should look like.</p> <p>12 THE WITNESS: Yeah, that's different.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Okay.</p> <p>15 A You changed it to "substance." But I</p> <p>16 mean what it should look like is what I'm talking</p> <p>17 about. It was -- it should look good, right? And</p> <p>18 so there should be like, you know, bold headings</p> <p>19 and there should be spaces where they belong.</p> <p>20 Q What's the name of the contact person</p> <p>21 you interfaced with at MSA?</p> <p>22 A My main one is Maddie Petta --</p> <p>23 Pettenati.</p> <p>24 Q Okay. And how long have you worked with</p> <p>25 Maddie Pettenati?</p>	<p style="text-align: right;">Page 176</p> <p>1 at MSA to help you get your report in order?</p> <p>2 MS. BROWN: Objection to the form,</p> <p>3 misstates the testimony.</p> <p>4 THE WITNESS: I don't recall the amount</p> <p>5 of time. I mean whatever it took. Like some of</p> <p>6 it might be like a two-minute conversation to say</p> <p>7 like, you know, I want to move a section down or</p> <p>8 something. Or, you know, Can you proofread that</p> <p>9 particular paragraph and look for typos? And</p> <p>10 things of that sort.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Did any of the folks at MSA make any</p> <p>13 suggestions with regard to the scientific or</p> <p>14 medical content of your report?</p> <p>15 MS. BROWN: Objection. Instruct not to</p> <p>16 answer on work product. You can discuss -- you</p> <p>17 can answer the question of whether you had any</p> <p>18 conversations, the substance of which is</p> <p>19 privileged, and I'll instruct you not to answer.</p> <p>20 MS. PARFITT: MSA is a third-party</p> <p>21 contractor from what I'm understanding.</p> <p>22 MS. BROWN: No different than if he was</p> <p>23 working with a secretary to format this.</p> <p>24 Conversations about drafts of the report are</p> <p>25 privileged and will not be discussed.</p>
<p style="text-align: right;">Page 175</p> <p>1 A A couple of years.</p> <p>2 Q Okay. Do you work with anyone else over</p> <p>3 at MSA to help you with your reports?</p> <p>4 A Oh, sure.</p> <p>5 MS. BROWN: Objection to the form.</p> <p>6 THE WITNESS: Yeah.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Who?</p> <p>9 A There's a woman named April, Shannon.</p> <p>10 I'm sure there's others too.</p> <p>11 Q What are their backgrounds?</p> <p>12 MS. BROWN: Objection to the form.</p> <p>13 THE WITNESS: Everybody has a -- a</p> <p>14 science background of some sort, like biology</p> <p>15 degrees, things of that sort.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Okay. How much time did you spend with</p> <p>18 the folks at -- the team at MSA for purposes of</p> <p>19 getting your report put together?</p> <p>20 A I don't know. I mean, what do you mean</p> <p>21 by "with"?</p> <p>22 Q Well, we know you've had conversations.</p> <p>23 We know that you have received information with</p> <p>24 regard to shaping your report, and what I want to</p> <p>25 know is, how much time did you spend with the team</p>	<p style="text-align: right;">Page 177</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Doctor, if you can answer the question.</p> <p>3 A Can you say it again? I'm sorry.</p> <p>4 Q Sure. No worries. I'm just getting it</p> <p>5 here.</p> <p>6 Did any of the folks at MSA make any</p> <p>7 suggestions with regard to the scientific or</p> <p>8 medical content of your report?</p> <p>9 MS. BROWN: I'm instructing you not to</p> <p>10 answer that question under the work-product</p> <p>11 privilege.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q Do you keep time records of the time you</p> <p>14 spend with MSA?</p> <p>15 A No.</p> <p>16 Q Okay. Well, I believe you testified at</p> <p>17 the beginning of your deposition that your charge</p> <p>18 per hour is \$485, correct?</p> <p>19 A Well, I was trying -- I was trying to</p> <p>20 make you understand that differently, and you said</p> <p>21 we would talk about it, so maybe we can. My</p> <p>22 charge is \$400 an hour.</p> <p>23 Q All right. Where does the 485 come</p> <p>24 from?</p> <p>25 A It's what I said before, right. They</p>

45 (Pages 174 to 177)

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<p>1 add \$85 when they bill somebody for my time.</p> <p>2 Q Who "they"?</p> <p>3 A MSA.</p> <p>4 Q "They," MSA?</p> <p>5 A Yeah.</p> <p>6 Q All right. So that I get it straight,</p> <p>7 you charge 400 -- \$400 for your time, correct?</p> <p>8 A Correct.</p> <p>9 Q And then your understanding is MSA</p> <p>10 charges an additional \$85 to someone for their</p> <p>11 assistance for you, correct?</p> <p>12 MS. BROWN: Objection to the form, calls</p> <p>13 for speculation.</p> <p>14 THE WITNESS: So it's -- I don't know --</p> <p>15 I don't know how they break it down, because they</p> <p>16 bill for different things, like they bill for</p> <p>17 photocopying, they bill for some administrative</p> <p>18 tasks separately. Whatever it is, it's their</p> <p>19 business model, and they -- they add that amount</p> <p>20 to the hourly rate.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q How much did Medical Science bill for</p> <p>23 their work, do you know?</p> <p>24 MS. BROWN: Objection. Calls for</p> <p>25 speculation.</p>	<p>1 and basically an amount. I don't have --</p> <p>2 A Like it --</p> <p>3 Q -- it's been blacked out.</p> <p>4 A It doesn't matter. I can still --</p> <p>5 MS. BROWN: It's been redacted for work</p> <p>6 product.</p> <p>7 THE WITNESS: I mean I can help you</p> <p>8 understand it if you want.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q All I really want to understand and get</p> <p>11 a better understanding, Dr. Diette, is the types</p> <p>12 of services that MSA provided you in order to</p> <p>13 file this -- prepare this report.</p> <p>14 A Yeah, I -- I listed those.</p> <p>15 Q Okay. Do they help you with all of your</p> <p>16 expert reports?</p> <p>17 A In what?</p> <p>18 Q Does MSA provide any type of service in</p> <p>19 any and all expert reports that you prepare in the</p> <p>20 context of litigation?</p> <p>21 A No.</p> <p>22 Q Okay. Do you have another go-to service</p> <p>23 to help you with the preparation of your expert</p> <p>24 services?</p> <p>25 MS. BROWN: Objection to form.</p>
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<p>1 THE WITNESS: You can tell if we look at</p> <p>2 the -- the invoices.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q Okay. They would bill the same number</p> <p>5 of -- well, let me ask for a clarification. Not</p> <p>6 all your work was done in conjunction with the</p> <p>7 assistance of Medical Science Affiliates, correct?</p> <p>8 MS. BROWN: Objection to the form.</p> <p>9 THE WITNESS: I mostly sat by myself.</p> <p>10 Yeah.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Okay. So the invoices that I have for</p> <p>13 you would not necessarily reflect all of the work</p> <p>14 that Medical Science Affiliates afforded you,</p> <p>15 correct?</p> <p>16 A That's incorrect.</p> <p>17 MS. BROWN: Objection to the form.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q Okay.</p> <p>20 A I mean that's what I was trying to offer</p> <p>21 you earlier is to try to understand the -- the</p> <p>22 bills. Because also when you add that comment</p> <p>23 about the amount of money in total, it wasn't all</p> <p>24 money that goes to me.</p> <p>25 Q Yeah. The bills that I have have a date</p>	<p>1 THE WITNESS: No. I do stuff on my own</p> <p>2 as well.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q All right. So there are cases where</p> <p>5 you've done the work by yourself, and there are</p> <p>6 cases like this particular case where you engage</p> <p>7 the services of MSA, correct?</p> <p>8 A That is --</p> <p>9 MS. BROWN: Objection to the form.</p> <p>10 THE WITNESS: -- correct.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Okay. And did MSA edit any of your --</p> <p>13 any of your -- did MSA edit your expert report?</p> <p>14 A Yeah.</p> <p>15 Q Okay. What kind of edits did they make?</p> <p>16 A Well, all sorts. Like I asked them to</p> <p>17 look for typos, for example.</p> <p>18 Q Right.</p> <p>19 A I just happen to be open to page 30 and</p> <p>20 31, and where you see that the -- there's like</p> <p>21 bulleted sections, when I wrote that, it was just</p> <p>22 one long impenetrable paragraph, and so they were</p> <p>23 nice enough to sort of break it into some chunks</p> <p>24 so it would be easier to read.</p> <p>25 Q Okay. Bear with me if I asked this</p>

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<p>1 before, but did MSA ever suggest any new sentences</p> <p>2 or study that you didn't previously insert in your</p> <p>3 paper?</p> <p>4 A I doubt a new study. It could be -- I</p> <p>5 mean we worked -- we worked pretty hard to make</p> <p>6 sure that I have the full list of studies, you</p> <p>7 know, acknowledged, and so if there was something</p> <p>8 I left off -- I mean I don't remember this</p> <p>9 specifically for this, but that would be a normal</p> <p>10 practice, right, like which is to say, you know,</p> <p>11 Oh, I saw in your list of papers that there's a</p> <p>12 Smith paper, should that be on here? Not them</p> <p>13 going out and saying, Oh, I found a Smith paper,</p> <p>14 would you like that on there?</p> <p>15 Q But they might looked at yours and say,</p> <p>16 You -- you missed a study. Fair?</p> <p>17 A Oh, sure.</p> <p>18 MS. BROWN: Objection to the form.</p> <p>19 THE WITNESS: Yeah.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Okay. And they might look at your</p> <p>22 report and say, You missed --</p> <p>23 I think what I'm getting at, Dr. Diette,</p> <p>24 you described their efforts as generally</p> <p>25 editorial. Is that fair?</p>	<p>1 Q And I'm not concerned about the format.</p> <p>2 What I'm concerned about is the substance,</p> <p>3 Dr. Diette, as you can appreciate.</p> <p>4 MS. BROWN: Objection.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q And so what I'm trying to -- to get some</p> <p>7 clarity here is that, other than perhaps providing</p> <p>8 you a study that you may have omitted from your</p> <p>9 report, is there anything else that falls more in</p> <p>10 the substantive area that they provided and</p> <p>11 offered for you?</p> <p>12 A I -- I think I've answered as best I</p> <p>13 can.</p> <p>14 Q Well, why don't we -- let's talk about</p> <p>15 your contact with J&J. When did they first reach</p> <p>16 out to you to talk with you about being an expert</p> <p>17 to defend them in these lawsuits?</p> <p>18 MS. BROWN: Objection to the form of the</p> <p>19 question.</p> <p>20 THE WITNESS: So they never asked me to</p> <p>21 defend them. They -- they asked me to evaluate</p> <p>22 the epidemiologic literature.</p> <p>23 And just to be clear, because it seemed</p> <p>24 like it was tripping us up before trying to talk</p> <p>25 about this, when I talk about J&J, it's lawyers</p>
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<p>1 MS. BROWN: Objection to the form.</p> <p>2 THE WITNESS: I would say administrative</p> <p>3 and editorial.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay. So we can agree that it's both</p> <p>6 administrative and editorial?</p> <p>7 MS. BROWN: Objection to the form.</p> <p>8 THE WITNESS: Correct.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q And as I appreciate, in addition to</p> <p>11 perhaps providing you with a study or two that --</p> <p>12 or three, however number, that you might have</p> <p>13 omitted, is there anything substantive like that</p> <p>14 that they did for you for purposes of your expert</p> <p>15 report?</p> <p>16 A I insist that they don't. I tell them</p> <p>17 that I don't want any intellectual input into</p> <p>18 the -- to the stuff that we're working on. Like I</p> <p>19 don't want their -- I don't even know if they have</p> <p>20 opinions, but I don't want their opinions. I</p> <p>21 literally want this to look like a professional</p> <p>22 product, and I want to get it done in a way that I</p> <p>23 can still spend my time -- my other professional</p> <p>24 time on other things. So if I were to try to make</p> <p>25 this look like this, it would take me forever.</p>	<p>1 that are working with J&J as opposed to somebody</p> <p>2 from J&J per se. And so I'll leave it to you guys</p> <p>3 to sort out what that -- what that means.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Fair enough.</p> <p>6 A But -- but the first time would have</p> <p>7 been a lawyer back in 2017 who asked if I would be</p> <p>8 interested in reviewing the epidemiologic</p> <p>9 literature.</p> <p>10 Q Who was that lawyer?</p> <p>11 A Jonathan Cooper.</p> <p>12 Q Okay. Now, at the time that Jonathan --</p> <p>13 or Jonathan Cooper contacted you, did you -- were</p> <p>14 you working with MSA?</p> <p>15 A Obviously, because I said ten years,</p> <p>16 and, you know, this was 2017.</p> <p>17 Q Okay. Did you share with Jonathan</p> <p>18 Cooper that you worked with this MSA company to</p> <p>19 help you prepare your expert reports?</p> <p>20 A He knew about it already, because I</p> <p>21 think the reason he reached out to me is because</p> <p>22 he was impressed with the work I had done in</p> <p>23 other -- other cases.</p> <p>24 Q Okay. Well, when he -- when you say he</p> <p>25 was impressed with you, with the work that you've</p>

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<p style="text-align: right;">Page 186</p> <p>1 done, when he -- let me explore that a little bit.</p> <p>2 When he called you, did you tell him</p> <p>3 that you had previously worked with MSA to help</p> <p>4 you with your expert reports?</p> <p>5 A I didn't have to.</p> <p>6 Q He knew that.</p> <p>7 A Yes.</p> <p>8 Q Okay. How would Mr. Cooper have known</p> <p>9 that you worked with MSA before?</p> <p>10 MS. BROWN: Objection to the form, calls</p> <p>11 for speculation.</p> <p>12 MR. LOCKE: Objection.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q If you know. Seems like you know.</p> <p>15 A Oh, I do. We had -- he and I had worked</p> <p>16 together on other cases.</p> <p>17 Q Okay. What other cases did you work</p> <p>18 with Mr. Cooper on?</p> <p>19 A They were asbestos-related cases with</p> <p>20 plastic or phenolics, like electrical equipment.</p> <p>21 Q Okay. And in those cases that you</p> <p>22 worked with Jonathan on -- or Mr. Cooper on, did</p> <p>23 you utilize the services of MSA as well to help</p> <p>24 you prepare your expert report in those cases?</p> <p>25 A I did.</p>	<p style="text-align: right;">Page 188</p> <p>1 Q Okay. Have they ever listed you on some</p> <p>2 type of website as a consultant for legal</p> <p>3 purposes?</p> <p>4 A Well, I see --</p> <p>5 MS. BROWN: Objection to the form,</p> <p>6 calls for speculation.</p> <p>7 THE WITNESS: -- Mr. Finch is here and</p> <p>8 he --</p> <p>9 THE REPORTER: Excuse me.</p> <p>10 THE WITNESS: Oh, sorry.</p> <p>11 MS. BROWN: Objection to the form, call</p> <p>12 for speculation. Thank you.</p> <p>13 THE WITNESS: Mr. Finch flashed</p> <p>14 something up at a trial to suggest that they had,</p> <p>15 but that wasn't an advertisement for me. It was a</p> <p>16 list of somebody who had credentials that were</p> <p>17 similar to mine.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q Okay. Well, my question is, have -- are</p> <p>20 you aware of whether or not Medical Science</p> <p>21 Affiliates has ever advertised your name out in</p> <p>22 the -- the community as someone --</p> <p>23 MS. BROWN: Same objection --</p> <p>24 BY MS. PARFITT:</p> <p>25 Q -- who was a specialist in pulmonology</p>
<p style="text-align: right;">Page 187</p> <p>1 Q Okay. Has MSA reached out to you and</p> <p>2 engaged or asked if you would engage in assisting</p> <p>3 them on any other projects currently?</p> <p>4 A What do you mean by "currently"?</p> <p>5 Q Well, are you working with MSA on any</p> <p>6 other projects other than the talcum powder</p> <p>7 products and ovarian cancer?</p> <p>8 A Yes.</p> <p>9 Q What projects?</p> <p>10 MS. BROWN: And again, Doctor, to the</p> <p>11 extent that a confidentiality agreement doesn't</p> <p>12 prevent you from disclosing other work that you're</p> <p>13 doing, you can answer the question.</p> <p>14 THE WITNESS: Some cases that relate to</p> <p>15 asbestos and other chemical-related cases.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Okay. Was there a time when you,</p> <p>18 instead of receiving services from MSA, you</p> <p>19 provided services to MSA as an affiliate expert?</p> <p>20 MS. BROWN: Objection to the form of the</p> <p>21 question.</p> <p>22 THE WITNESS: I know they have that word</p> <p>23 "affiliate" in their name. I don't know what that</p> <p>24 means. But I don't provide services to them.</p> <p>25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 189</p> <p>1 medicine?</p> <p>2 MS. BROWN: Same objection.</p> <p>3 THE WITNESS: I'm not aware that they</p> <p>4 advertise.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Okay. So are there times that Medical</p> <p>7 Science Affiliates reaches out to you and says,</p> <p>8 Dr. Diette, we want you to do a medical -- a</p> <p>9 scientific review for us on a topic?</p> <p>10 A Never.</p> <p>11 Q Okay. They've never done that. You've</p> <p>12 never provided that service for them.</p> <p>13 A They -- they don't ask me to do work for</p> <p>14 them.</p> <p>15 Q Okay. Do their clients ask you to do</p> <p>16 work for them?</p> <p>17 A Of course, that's where we started,</p> <p>18 right, from ten years ago.</p> <p>19 Q Right. And that's what I'm trying to</p> <p>20 figure out.</p> <p>21 MS. BROWN: Let him finish. I don't</p> <p>22 think he was done.</p> <p>23 THE WITNESS: No, that was -- that was</p> <p>24 the description of what I was saying, like how</p> <p>25 the -- the first time that I met them was that</p>

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<p style="text-align: right;">Page 190</p> <p>1 they -- there was some, you know, group that</p> <p>2 wanted an epidemiologic review, and they were</p> <p>3 trying to figure out if there were local</p> <p>4 epidemiologists that could take on a task like</p> <p>5 that, and so that's the way it worked.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Okay. So I now get --</p> <p>8 MS. BROWN: He is not done.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q Are you done, Doctor? I thought you</p> <p>11 were.</p> <p>12 A I'll be done.</p> <p>13 Q Okay. So if I appreciate this</p> <p>14 structure, so we can move on, a client, some</p> <p>15 company can reach out to Medical Science</p> <p>16 Affiliates and say, We need some work done and</p> <p>17 research done on a particular area. Will you do</p> <p>18 that for me?</p> <p>19 Medical Science Affiliates will say,</p> <p>20 Yes, we can. And then Medical Science Affiliates</p> <p>21 reaches out to people like you?</p> <p>22 MS. BROWN: Objection to the form.</p> <p>23 THE WITNESS: So I don't know -- I don't</p> <p>24 know when they say, Yes, we can. Like I don't</p> <p>25 know, for example -- like their -- I don't know</p>	<p style="text-align: right;">Page 192</p> <p>1 Q So you never work for MSA; you always</p> <p>2 work for a corporate client?</p> <p>3 MR. LOCKE: Objection.</p> <p>4 MS. BROWN: Objection to the form of the</p> <p>5 question.</p> <p>6 THE WITNESS: So I've never worked for</p> <p>7 MSA.</p> <p>8 BY MS. PARFITT:</p> <p>9 Q Who pays your bills? Law firms?</p> <p>10 MS. BROWN: Objection to the form.</p> <p>11 THE WITNESS: So --</p> <p>12 MS. BROWN: What bills? What are you</p> <p>13 talking about?</p> <p>14 BY MS. PARFITT:</p> <p>15 Q Who pays your bills for doing services</p> <p>16 at the request of MSA?</p> <p>17 MS. BROWN: Objection to the form.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q Anybody?</p> <p>20 MS. BROWN: Objection. Can we -- let's</p> <p>21 have one question and let him answer.</p> <p>22 Go ahead.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q And I'll tell you the reason I'm asking,</p> <p>25 Dr. Diette.</p>
<p style="text-align: right;">Page 191</p> <p>1 what their size is, but they may say, Yes, we can,</p> <p>2 and just do it themselves. Right. They have</p> <p>3 other people that I don't work with that work</p> <p>4 there.</p> <p>5 I'm just saying, like you're asking the</p> <p>6 question, so it's like -- so if somebody calls</p> <p>7 them and says, Can you do this work? They may</p> <p>8 well say, Yes, we can do it. They may or may not</p> <p>9 need a content expert or methodologic expert to do</p> <p>10 it. So it -- I assume it depends, but I'm -- I'm</p> <p>11 not familiar with their entire business operation.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q Okay. All I'm trying to find out is --</p> <p>14 is who comes to who, and from what I understand</p> <p>15 your testimony is, a client will reach out to MSA</p> <p>16 and say, We have a project. MSA will determine</p> <p>17 whether or not someone -- someone's expertise is</p> <p>18 needed in order to complete that job, and then MSA</p> <p>19 reaches out to you. Is that fair?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 MS. BROWN: Objection. Speculation.</p> <p>22 THE WITNESS: I like the answer I just</p> <p>23 gave. I mean I think that really was my answer to</p> <p>24 that exact question.</p> <p>25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 193</p> <p>1 MS. BROWN: No, no, no, no. You ask the</p> <p>2 question, he answers. We don't need to know why</p> <p>3 you're asking the question.</p> <p>4 MS. PARFITT: Excuse me.</p> <p>5 MS. BROWN: It's improper. You're not</p> <p>6 going to give a speech, Counsel.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Dr. Diette, we -- has there ever been a</p> <p>9 chance or an opportunity where you have reached</p> <p>10 out to MSA on your own, and say, A client that</p> <p>11 doesn't work or do business with you, MSA, has</p> <p>12 asked me to do a report. Can you help me?</p> <p>13 A Yes.</p> <p>14 Q Okay. So that's one scenario, correct?</p> <p>15 A Correct.</p> <p>16 Q It's some other client has -- some other</p> <p>17 individual or entity has reached out to you and</p> <p>18 said, Dr. Diette, I would like to engage your</p> <p>19 expertise in the legal context. Fair?</p> <p>20 MS. BROWN: Objection to the form.</p> <p>21 THE WITNESS: Or the epidemiologic</p> <p>22 context, but in some context.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Okay. And then you have in turn reached</p> <p>25 out to MSA and said, I need some help.</p>

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<p>1 MS. BROWN: Objection to the form.</p> <p>2 THE WITNESS: Something like that, yeah.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q Okay. That's one scenario.</p> <p>5 Another scenario is when a corporate</p> <p>6 client, for instance, engages the services of MSA</p> <p>7 to do a project and a particular expertise is</p> <p>8 needed, and MSA then reaches out to folks like</p> <p>9 yourself or folks in other medical specialties.</p> <p>10 Fair?</p> <p>11 MS. BROWN: Objection. Speculation.</p> <p>12 THE WITNESS: So I'm not a lawyer,</p> <p>13 right. So I'm trying to listen carefully to the</p> <p>14 words that you're using, and when you say they</p> <p>15 reach out and they retain MSA, I -- I actually</p> <p>16 don't know if that's actually what happens, right.</p> <p>17 So I gave you an example that --</p> <p>18 BY MS. PARFITT:</p> <p>19 Q Okay.</p> <p>20 A -- they might retain MSA for their own</p> <p>21 purposes, and nobody else gets involved. If like,</p> <p>22 for example, in this case when Jonathan Cooper</p> <p>23 reached out, he wanted to work with me, and MSA</p> <p>24 provided the support services for me to get that</p> <p>25 work done. So I -- I have no idea whether he</p>	<p>1 conflicts checks?</p> <p>2 MS. BROWN: Objection. Speculation.</p> <p>3 Engaged by who?</p> <p>4 BY MS. PARFITT:</p> <p>5 Q When you're engaged by a client, who</p> <p>6 does the conflict --</p> <p>7 MS. BROWN: Same --</p> <p>8 BY MS. PARFITT:</p> <p>9 Q -- conflicts checks for you?</p> <p>10 MS. BROWN: Same objection.</p> <p>11 THE WITNESS: I don't know that anybody</p> <p>12 does conflicts checks. I mean if there is</p> <p>13 somebody, I'm not aware of who that is. If it</p> <p>14 comes up, people will ask me sometimes if I have a</p> <p>15 conflict of interest. Sometimes I'll see a</p> <p>16 complaint, you know, and be asked to look at, you</p> <p>17 know, the names on the complaint.</p> <p>18 It all depends, but I -- I don't even</p> <p>19 know if I know what a conflict checks is, I mean</p> <p>20 if that's a technical term. It's only been --</p> <p>21 it's only been done the way I'm describing, which</p> <p>22 somebody will say to me like, you know, Do you</p> <p>23 have any conflict of interest?</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Okay. You prepared two affidavits that</p>
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<p>1 retained MSA per se. I mean that's -- that's</p> <p>2 something for lawyers to kind of sort through.</p> <p>3 Q Well, did Jonathan Cooper go to you</p> <p>4 directly or did Jonathan Cooper go to MSA?</p> <p>5 MS. BROWN: Objection to the form.</p> <p>6 You can answer if you know.</p> <p>7 THE WITNESS: It was kind of both. I</p> <p>8 mean I think we -- we were talking about something</p> <p>9 else one day, and he asked if I would be</p> <p>10 interested in this.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Okay. And did Jonathan Cooper then</p> <p>13 reach out to MSA as well?</p> <p>14 MS. BROWN: Objection. Speculation.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q You said both. That's why I'm asking.</p> <p>17 A Yeah, yeah, I mean --</p> <p>18 MS. BROWN: Same objection.</p> <p>19 THE WITNESS: I don't know how that part</p> <p>20 worked, I mean, but -- but it was pretty clear</p> <p>21 that it was such a big volume of work, that if I</p> <p>22 was going to do it with him that I was going to</p> <p>23 use MSA's services.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q When you're engaged, who does the</p>	<p>1 I'm aware of, one in the Ingham case and one in</p> <p>2 the Forrest. Do you recall doing that back in</p> <p>3 2018?</p> <p>4 A I do.</p> <p>5 Q Okay. Are you aware of any other</p> <p>6 affidavits you prepared in 2018 other than the</p> <p>7 Ingham and the Forrest?</p> <p>8 A I don't think so. But I mean if you</p> <p>9 have one, I would be glad to help confirm it, but</p> <p>10 I can't recall one off the top of my head.</p> <p>11 Q Fair enough. How much did you charge</p> <p>12 for preparation of the Ingham affidavit?</p> <p>13 MS. BROWN: Objection to the form.</p> <p>14 THE WITNESS: I don't remember.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q More than 50,000?</p> <p>17 MS. BROWN: Same objection.</p> <p>18 THE WITNESS: So I guess it depends upon</p> <p>19 when we're talking about like me, you know,</p> <p>20 because earlier you were lumping together, you</p> <p>21 know, services that MSA charges for and gets paid</p> <p>22 for. So I don't remember what -- what part I got.</p> <p>23 It wouldn't -- it wouldn't have taken \$50,000</p> <p>24 worth of my time to prepare, you know, the</p> <p>25 affidavit, I don't think. And in part, because,</p>

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<p style="text-align: right;">Page 198</p> <p>1 you know, the input for that was stuff I was</p> <p>2 already, you know, reading and interpreting</p> <p>3 otherwise.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q All right. How much did you charge for</p> <p>6 the Forrest report?</p> <p>7 MS. BROWN: Objection to the form.</p> <p>8 THE WITNESS: The same -- same answer.</p> <p>9 I don't know. And in fact, the Forrest report, if</p> <p>10 it came second, probably not very much because I</p> <p>11 think it's mostly derivative from the first. I</p> <p>12 mean I try -- I'm not trying to just, you know,</p> <p>13 create work to create it. Like if there's</p> <p>14 something I -- that I like the way it reads, I try</p> <p>15 to use it again.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Okay. Are you aware, having actually</p> <p>18 prepared both of those affidavits, they are</p> <p>19 virtually the same affidavit? Would that surprise</p> <p>20 you?</p> <p>21 MS. BROWN: Objection to the form.</p> <p>22 THE WITNESS: I hope they are. I mean</p> <p>23 that -- that was the intent.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Okay. Other than the ovarian cancer/</p>	<p style="text-align: right;">Page 200</p> <p>1 products and ovarian cancer.</p> <p>2 And the question I have is, in any</p> <p>3 context, when the topic of interest is talcum</p> <p>4 powder products and ovarian cancer, have you ever</p> <p>5 been asked by MSA to do any work that's</p> <p>6 non-pulmonary, other than the ovarian cancer</p> <p>7 cases?</p> <p>8 A Related --</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: Related to talcum powder?</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Related to anything.</p> <p>13 A Well, wait a minute. No, because -- so,</p> <p>14 first of all, you said has MSA asked me to do it.</p> <p>15 Like they don't ask me to do stuff. Like they --</p> <p>16 it's -- the relationship we described before is</p> <p>17 what it is. So if it's more general about are</p> <p>18 there other cases --</p> <p>19 Q Yeah.</p> <p>20 A -- and when you say non-pulmonary, you</p> <p>21 know, there are cases I've been involved in that</p> <p>22 have nothing do with talcum powder that are</p> <p>23 non-pulmonary.</p> <p>24 So I'm just trying to figure out,</p> <p>25 there's a lot of different angles to what -- to</p>
<p style="text-align: right;">Page 199</p> <p>1 talcum powder cases, have you been engaged by</p> <p>2 anyone else for opinions on a non-pulmonary issue?</p> <p>3 MS. BROWN: Objection to the form.</p> <p>4 THE WITNESS: Related to?</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Your work with MSA.</p> <p>7 A No, but you said -- it sounded like</p> <p>8 there's something missing from the question.</p> <p>9 Q Sure. Let me -- let me ask it again.</p> <p>10 Okay.</p> <p>11 Other than this case involving ovarian</p> <p>12 cancer and talcum powder products, have you been</p> <p>13 asked and -- or requested by anyone for your</p> <p>14 opinions on a topic that was something other than</p> <p>15 non-pulmonary?</p> <p>16 MS. BROWN: Objection. Do you mean --</p> <p>17 MS. PARFITT: That was non-pulmonary.</p> <p>18 MS. BROWN: -- to exclude Ingham and the</p> <p>19 other? When you say "this case," do you mean just</p> <p>20 the MDL?</p> <p>21 MS. PARFITT: Yeah.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q And I think that's where we're getting</p> <p>24 hung up. When I say "this case," I'm going to be</p> <p>25 talking about "this case" being talcum powder</p>	<p style="text-align: right;">Page 201</p> <p>1 what you're asking.</p> <p>2 Q Sure.</p> <p>3 A Are you talking about talcum powder</p> <p>4 cases that are related to something other than</p> <p>5 ovarian cancer, and something other than a</p> <p>6 pulmonary --</p> <p>7 Q I'll simplify it. Have you ever</p> <p>8 prepared a report in a -- let me do it this way.</p> <p>9 Talcum powder products and ovarian</p> <p>10 cancer have nothing to do with pulmonary medicine,</p> <p>11 correct?</p> <p>12 MS. BROWN: Objection to the form. Are</p> <p>13 we abandoning inhalation as a theory of --</p> <p>14 MS. PARFITT: No, we're not, no.</p> <p>15 MS. BROWN: Okay.</p> <p>16 THE WITNESS: Then no. I mean, no,</p> <p>17 meaning that if that's a theory, then that</p> <p>18 certainly has something to do with pulmonary</p> <p>19 medicine.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Okay. And I think what I'm really</p> <p>22 driving at is, it looks as though your focus for</p> <p>23 the last couple of years has been talcum powder</p> <p>24 products and ovarian cancer or asbestos and</p> <p>25 mesothelioma. Is that fair?</p>

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<p style="text-align: right;">Page 202</p> <p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: My focus --</p> <p>3 BY MS. PARFITT:</p> <p>4 Q Focus and research --</p> <p>5 MS. BROWN: Objection.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q -- for preparation of expert legal</p> <p>8 reports.</p> <p>9 MS. BROWN: Objection to the form.</p> <p>10 THE WITNESS: I -- I'm either not</p> <p>11 hearing you well or I think things are getting</p> <p>12 jumbled.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Okay.</p> <p>15 A And I --</p> <p>16 Q Probably the -- the latter.</p> <p>17 A No, and I apologize.</p> <p>18 Q It's probably me.</p> <p>19 A I'm not trying to give you a hard time.</p> <p>20 I just mean that -- what I -- what I heard earlier</p> <p>21 is am I working on something with talcum powder</p> <p>22 other than ovarian cancer or other than ovarian</p> <p>23 cancer and something that isn't part of the lung?</p> <p>24 Is that it?</p> <p>25 Q Are you preparing expert reports on a</p>	<p style="text-align: right;">Page 204</p> <p>1 anything --</p> <p>2 Q Do you want to take --</p> <p>3 A No, I'm just wondering. Not</p> <p>4 necessarily, but if it's --</p> <p>5 MS. MILLER: This would be a good time</p> <p>6 for lunch.</p> <p>7 THE WITNESS: Yeah, that's what I'm</p> <p>8 wondering, just if it's going to be --</p> <p>9 MS. BROWN: Yeah, it's up to you. If</p> <p>10 you want to break, counsel will give you a break.</p> <p>11 MS. PARFITT: Whatever you want to do.</p> <p>12 Do you want to take a break now?</p> <p>13 THE WITNESS: It would be nice to -- to</p> <p>14 get a snack, and --</p> <p>15 MS. PARFITT: You want to take a half</p> <p>16 hour and grab --</p> <p>17 THE WITNESS: Would that be okay?</p> <p>18 MS. PARFITT: That's totally fine, yep.</p> <p>19 THE VIDEOGRAPHER: The time is 12:08</p> <p>20 p.m., and we are going off the record.</p> <p>21 (Lunch recess.)</p> <p>22 THE VIDEOGRAPHER: The time is 12:43</p> <p>23 p.m., and we're back on the record.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Good afternoon, Dr. Diette.</p>
<p style="text-align: right;">Page 203</p> <p>1 topic area other than talcum powder products and</p> <p>2 ovarian cancer currently?</p> <p>3 MS. BROWN: Objection. He's not</p> <p>4 answering questions about reports that have not</p> <p>5 been served in cases --</p> <p>6 MS. PARFITT: Understood.</p> <p>7 MS. BROWN: -- where he's not a</p> <p>8 disclosed expert.</p> <p>9 THE WITNESS: You mean in my</p> <p>10 professional life in general?</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Correct.</p> <p>13 A Yes.</p> <p>14 Q Okay. What other areas?</p> <p>15 A Well, that's what we talked about</p> <p>16 before, right. So there was asbestos, there's</p> <p>17 some chemicals, probably like mold and dampness.</p> <p>18 There's malpractice cases. I mean a whole variety</p> <p>19 of different things.</p> <p>20 Q Okay. All right. I want to come to --</p> <p>21 where I want to go is your -- your actual report.</p> <p>22 I want you to take me through -- I'll ask you some</p> <p>23 questions about the process that you went through</p> <p>24 in actually putting this report together.</p> <p>25 A And I don't want to overbreak or</p>	<p style="text-align: right;">Page 205</p> <p>1 A Good afternoon.</p> <p>2 Q All right, Dr. Diette, I'd like to focus</p> <p>3 for a little bit about your -- actually your</p> <p>4 expert report and hopefully get to your opinions</p> <p>5 here soon.</p> <p>6 It's fair to say that this report is --</p> <p>7 this expert report is not a report that you</p> <p>8 prepared in the ordinary course of your activities</p> <p>9 as a pulmonary medicine at Johns Hopkins?</p> <p>10 MS. BROWN: Objection to the form.</p> <p>11 THE WITNESS: That's correct.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q Okay. And are all the opinions which</p> <p>14 you will be sharing with us today, and eventually</p> <p>15 the court and a jury, set forth in your -- your</p> <p>16 expert report?</p> <p>17 MS. BROWN: Form.</p> <p>18 THE WITNESS: I hope so. I mean,</p> <p>19 it's -- there may be like -- like smaller opinions</p> <p>20 that are underpinnings that I didn't capture, but</p> <p>21 I mean the fundamental opinions should be there.</p> <p>22 And assuming nothing different comes out when</p> <p>23 you're asking me about it today, I guess the only</p> <p>24 other thing I'd say is that I don't think that</p> <p>25 I've seen all of the -- the testimony yet in this</p>

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<p>1 case. So I don't know whether that's going to,</p> <p>2 you know, spur some other thought, you know, from</p> <p>3 the other -- other experts who are testifying, but</p> <p>4 aside from that, then this should otherwise be</p> <p>5 complete.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q And obviously if you see something,</p> <p>8 testimony that causes you to change your opinions,</p> <p>9 you will let me know, correct?</p> <p>10 MS. BROWN: Form.</p> <p>11 THE WITNESS: I will.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q All right. Dr. Diette, on the front of</p> <p>14 your report it says "Expert Report of Gregory</p> <p>15 Diette, MD, MHS, For General Causation Daubert</p> <p>16 Hearing." Did you write that?</p> <p>17 A Not this page, no.</p> <p>18 Q All right. Who wrote that?</p> <p>19 MS. BROWN: Objection to the form.</p> <p>20 THE WITNESS: I -- I don't know</p> <p>21 literally. I think this came from the law firm as</p> <p>22 a cover page for me to -- to sign.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q You've testified both in general</p> <p>25 causation case -- as a general causation witness</p>	<p>1 to say that that is your signature on the -- on</p> <p>2 the front page, Gregory Diette?</p> <p>3 A Yes, it is.</p> <p>4 Q And you completed that on February 25th,</p> <p>5 2019, correct?</p> <p>6 A Exactly right.</p> <p>7 Q Okay. And it would also -- is it also</p> <p>8 fair to say that the opinions contained in this</p> <p>9 report are not the opinions of Johns Hopkins</p> <p>10 University?</p> <p>11 A Not as far as I know. I mean they're</p> <p>12 literally just mine.</p> <p>13 Q Have you shared these opinions with any</p> <p>14 of the other members of the Johns Hopkins</p> <p>15 community?</p> <p>16 A No.</p> <p>17 Q All right. Did you run the opinions</p> <p>18 that you have by any of the staff or your</p> <p>19 superiors at Johns Hopkins?</p> <p>20 MS. BROWN: Objection to the form.</p> <p>21 THE WITNESS: No.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Okay. Aside from this expert report and</p> <p>24 the opinions retained herein, have you shared your</p> <p>25 opinions with anyone else outside of the Johns</p>
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<p>1 and as well as a specific causation witness,</p> <p>2 correct?</p> <p>3 A Generally speaking, like in legal cases?</p> <p>4 Q Correct.</p> <p>5 A Yes, I have.</p> <p>6 Q All right. So you understand the</p> <p>7 difference.</p> <p>8 A I hope so, yeah.</p> <p>9 Q Okay. Have you actually testified in an</p> <p>10 asbestos/meso- -- mesothelioma case on giving</p> <p>11 specific causation opinions?</p> <p>12 A Yes.</p> <p>13 Q Okay. Have you also provided general</p> <p>14 causation opinions in a meso/asbestos case?</p> <p>15 A Yes.</p> <p>16 Q Okay. Now, it says Daubert. Do you</p> <p>17 understand what a Daubert hearing is?</p> <p>18 MS. BROWN: Objection to the form.</p> <p>19 THE WITNESS: Probably not the way that</p> <p>20 you do. I have a general -- general sense of</p> <p>21 this, but -- you know, I -- I wouldn't be able to</p> <p>22 answer, you know, a lot of test questions about</p> <p>23 it.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Okay. All right. And would it be fair</p>	<p>1 Hopkins community, regulatory or scientific</p> <p>2 bodies?</p> <p>3 MS. BROWN: Objection to the form.</p> <p>4 THE WITNESS: No. You mean other than</p> <p>5 the lawyers and --</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Correct, other than your lawyers.</p> <p>8 A Oh, yeah, yeah, yeah.</p> <p>9 MS. BROWN: Objection to the form.</p> <p>10 We're not his lawyers.</p> <p>11 THE WITNESS: Right, but I mean but</p> <p>12 lawyers that are involved in this case, I have</p> <p>13 expressed it to, but not those other kinds of</p> <p>14 entities that you described.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. And to be clear, you have not</p> <p>17 shared with the Johns Hopkins community your</p> <p>18 opinions on talcum powder products and ovarian</p> <p>19 cancer.</p> <p>20 MS. BROWN: Objection to the form.</p> <p>21 THE WITNESS: That is correct.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Okay. Let's go to I believe page 2 of</p> <p>24 your report, if you will.</p> <p>25 And take a moment. Do you have that in</p>

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<p>1 front of you?</p> <p>2 A I do. Thank you.</p> <p>3 Q Okay. Is it fair to say that your</p> <p>4 report contains the bases for your opinions as</p> <p>5 well?</p> <p>6 A Yes.</p> <p>7 Q All right. And is it fair the -- do you</p> <p>8 know whether or not this report has answered all</p> <p>9 the questions that J&J asked you to answer for</p> <p>10 them?</p> <p>11 MS. BROWN: Objection. Lacks</p> <p>12 foundation.</p> <p>13 THE WITNESS: Well, I think there's only</p> <p>14 one question, right?</p> <p>15 BY MS. PARFITT:</p> <p>16 Q And what was that question?</p> <p>17 MS. BROWN: Wait. Let him finish.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q What was that question?</p> <p>20 A I'm sorry. So the question was -- was</p> <p>21 really about whether or not the -- what does the</p> <p>22 epidemiologic evidence say about the relationship</p> <p>23 between talcum powder and ovarian cancer.</p> <p>24 Q All right. So let's turn to your</p> <p>25 report, page 2, and I believe --</p>	<p>1 Q Okay. And if you would turn -- be so</p> <p>2 kind to turn to the last page of the report,</p> <p>3 page 51.</p> <p>4 A Okay.</p> <p>5 Q And again, if you would read the first</p> <p>6 paragraph.</p> <p>7 A At the --</p> <p>8 Q And we'll go ahead and put that up on</p> <p>9 the ELMO.</p> <p>10 A Under "Conclusion" or the --</p> <p>11 Q Under the Conclusion, if you will.</p> <p>12 A Yep. The whole thing?</p> <p>13 Q Just that -- just that first</p> <p>14 paragraph -- or first sentence.</p> <p>15 A First sentence. Oh, okay. Yep.</p> <p>16 "It is my opinion, based on my</p> <p>17 qualifications and my extensive review of the</p> <p>18 available epidemiology studies and scientific</p> <p>19 literature, that there is not sufficient evidence</p> <p>20 to conclude that there is a causal relationship</p> <p>21 between perineal talcum powder exposure and</p> <p>22 ovarian cancer."</p> <p>23 Q Okay. And I know you have much to say</p> <p>24 about that, but that is basically the -- the</p> <p>25 general opinion that you're going to be sharing,</p>
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<p>1 MS. PARFITT: And we'll put it up on the</p> <p>2 ELMO here.</p> <p>3 (Counsel conferring.)</p> <p>4 MS. PARFITT: I guess we won't put it up</p> <p>5 on the ELMO here.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Looking at the Summary of Opinions,</p> <p>8 would you please read, if you will, that first</p> <p>9 sentence.</p> <p>10 A Down at the bottom?</p> <p>11 Q Please.</p> <p>12 A "The body of"?</p> <p>13 Q Under "Summary of Opinions."</p> <p>14 A Yep, sure.</p> <p>15 "The body of relevant epidemiological</p> <p>16 evidence does not support a causal connection</p> <p>17 between perineal use of talcum powder products,"</p> <p>18 parentheses, "whatever constituents those products</p> <p>19 may contain in addition to talc," end parentheses,</p> <p>20 "and ovarian cancer."</p> <p>21 Q All right. And then in the next page is</p> <p>22 you talk about the bases for that, correct?</p> <p>23 A I think that's the right way to say the</p> <p>24 bases. I mean it's sort of an elaboration of that</p> <p>25 general -- general opinion.</p>	<p>1 correct?</p> <p>2 A I agree with you, yes.</p> <p>3 Q Okay. Let me show you what we'll have</p> <p>4 marked as 12, Exhibit 12.</p> <p>5 (Counsel conferring.)</p> <p>6 MS. PARFITT: Let me show you, Counsel,</p> <p>7 what we -- what we'll have marked as Exhibit 12.</p> <p>8 There you go.</p> <p>9 (Diette Exhibit No. 12 was marked</p> <p>10 for identification.)</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Doctor, have you seen this before?</p> <p>13 A Let me take a look and see. (Peruses</p> <p>14 document.)</p> <p>15 So generally speaking, yes. The -- the</p> <p>16 only reason I can't say for sure I've literally</p> <p>17 seen this exact version is because that -- not</p> <p>18 that I would know when it was updated otherwise,</p> <p>19 but I don't know who's in charge of all these</p> <p>20 different -- excuse me -- websites that you found</p> <p>21 at Johns Hopkins, and so I don't know, you know,</p> <p>22 whether what I looked at is literally identical to</p> <p>23 what we're looking at here.</p> <p>24 Q All right.</p> <p>25 A But it's approximately something that</p>

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<p style="text-align: right;">Page 214</p> <p>1 I've seen.</p> <p>2 Q Okay. Fair.</p> <p>3 Now, this is from the Sidney Kimmel</p> <p>4 Comprehensive Cancer Center, correct?</p> <p>5 A That's right.</p> <p>6 Q And it's entitled "Risk Factors -- Risk</p> <p>7 Factors" -- excuse me -- and Symptoms." Do you</p> <p>8 see that?</p> <p>9 A I do.</p> <p>10 Q All right. And if you and this is for</p> <p>11 ovarian cancer, you see that?</p> <p>12 On the second line, "ovarian cancer," it</p> <p>13 talks --</p> <p>14 A Yes.</p> <p>15 Q Okay. Now, what I'd like you to do is</p> <p>16 turn to the second page, and there is a risk</p> <p>17 factor listed, amongst others. Do you see that?</p> <p>18 A I do.</p> <p>19 Q And it says "Talcum Powder and</p> <p>20 Asbestos." Do you see that?</p> <p>21 A Yes.</p> <p>22 Q All right. Would you read that, please.</p> <p>23 A "Habitual use of talcum powder on the</p> <p>24 genital area may increase the risk for ovarian</p> <p>25 cancer, but the evidence is not strong. A study"</p>	<p style="text-align: right;">Page 216</p> <p>1 up here, and I'm going to doc- -- and I'm going to</p> <p>2 go ahead and make a notation as you talk, and</p> <p>3 we're going to put your initials by that which you</p> <p>4 agree or don't agree, or that which resonates with</p> <p>5 you or that which does not.</p> <p>6 So give me a moment. Hang with me,</p> <p>7 okay?</p> <p>8 A Yeah.</p> <p>9 Q All right.</p> <p>10 MS. BROWN: Objection to the exercise.</p> <p>11 THE WITNESS: And I will say -- I mean I</p> <p>12 wasn't -- you know, that I don't necessarily --</p> <p>13 I'm not going to be able to necessarily agree or</p> <p>14 literally disagree with each one of these, but</p> <p>15 I'll just try to comment on what they -- what they</p> <p>16 have here and what it says to me.</p> <p>17 BY MS. PARFITT:</p> <p>18 Q All right. Well, why don't we take the</p> <p>19 first one.</p> <p>20 "Habitual use of talcum powder on the</p> <p>21 genital area may increase the risk for ovarian</p> <p>22 cancer, but the evidence is not strong."</p> <p>23 A Yeah.</p> <p>24 Q Do you agree with that?</p> <p>25 A I agree that the evidence is not strong.</p>
<p style="text-align: right;">Page 215</p> <p>1 -- the first sentence or the whole thing?</p> <p>2 Q The whole thing.</p> <p>3 A Yep. "A study at Harvard Medical School</p> <p>4 found that using talc this way doubled the risk,</p> <p>5 but other studies found no increased risk. Some</p> <p>6 researchers believe that talc may be carcinogenic</p> <p>7 because it contains particles of asbestos, a known</p> <p>8 carcinogen. It's been shown that rates of ovarian</p> <p>9 cancer are higher than normal in women whose jobs</p> <p>10 expose them to asbestos."</p> <p>11 Q All right. Thank you.</p> <p>12 Fair to say, Dr. Diette, that your</p> <p>13 opinions are contrary to the opinions of what --</p> <p>14 of those individuals at the Sidney Kimmel</p> <p>15 Comprehensive Cancer Center?</p> <p>16 MS. BROWN: Objection to the form of the</p> <p>17 question, lacks foundation.</p> <p>18 THE WITNESS: I wouldn't say globally.</p> <p>19 I mean there's -- there's things here that</p> <p>20 resonate with me just fine.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q What resonates with you fine and what</p> <p>23 does not resonate with you?</p> <p>24 A Well, so, for example, when --</p> <p>25 Q And if you will, I'm going to put mine</p>	<p style="text-align: right;">Page 217</p> <p>1 And -- and I think it's a -- it's a pretty nuanced</p> <p>2 statement. It may increase, which leaves open</p> <p>3 that it may not increase. So I think it's a --</p> <p>4 it's a balanced statement. And their inclusion of</p> <p>5 the evidence not being strong is what resonates</p> <p>6 with me.</p> <p>7 Q Okay. Do you disagree, though, that</p> <p>8 it -- do you agree or disagree with this</p> <p>9 statement: "Habitual use of talcum powder on the</p> <p>10 genital area may increase the risk for ovarian</p> <p>11 cancer, but the evidence is not strong"?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Do you agree with that statement?</p> <p>15 A I don't literally agree or disagree with</p> <p>16 it. I mean, I think I break it down the way that</p> <p>17 I did into those two parts.</p> <p>18 Q Okay. Well, I have a different</p> <p>19 question. I know how you want to do it, but I --</p> <p>20 I do get the ask the questions.</p> <p>21 MS. BROWN: He answered your question,</p> <p>22 Counsel.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Habitual question -- yes or no --</p> <p>25 MS. BROWN: No.</p>

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<p style="text-align: right;">Page 218</p> <p>1 BY MS. PARFITT:</p> <p>2 Q "Habitual use of talcum powder on the</p> <p>3 genital area may increase the risk for ovarian</p> <p>4 cancer." True or false?</p> <p>5 MR. LOCKE: Objection.</p> <p>6 MS. BROWN: Objection to the form of the</p> <p>7 question, asked and answered.</p> <p>8 You can give the same answer again.</p> <p>9 THE WITNESS: It's --</p> <p>10 MS. PARFITT: Counsel, please quit</p> <p>11 instructing the witness.</p> <p>12 MS. BROWN: Counsel, don't yell at me.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Go ahead.</p> <p>15 MS. BROWN: We can call the Judge.</p> <p>16 MS. PARFITT: I'm not yelling -- we can</p> <p>17 call the Judge because I'll tell you, I don't</p> <p>18 think he'll be -- she will be impressed.</p> <p>19 MS. BROWN: That's fine. Let's go.</p> <p>20 Let's walk right there and call her right now.</p> <p>21 MS. PARFITT: I'm not going to waste the</p> <p>22 time right now.</p> <p>23 MS. BROWN: Okay.</p> <p>24 THE WITNESS: So I don't see it as a</p> <p>25 true or false questions. I think that there's two</p>	<p style="text-align: right;">Page 220</p> <p>1 than "may increase the risk," and it's very</p> <p>2 different than saying it causes it.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q Okay.</p> <p>5 A So it's -- it's a pretty vague</p> <p>6 statement.</p> <p>7 Q Okay. And I think -- I hear what you're</p> <p>8 saying, but my question, and I think you just</p> <p>9 answered it, is if -- if Judge Wolfson says to</p> <p>10 you, Dr. Diette, I would like an answer to my</p> <p>11 question: Does the habitual use of talcum powder</p> <p>12 on the genital area increase the risk for ovarian</p> <p>13 cancer?</p> <p>14 My -- my question to you from Judge</p> <p>15 Wolfson.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 MS. BROWN: Objection to the form of the</p> <p>18 question, asked and answered.</p> <p>19 THE WITNESS: And whether it does?</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Yeah, the question is --</p> <p>22 A Well, it doesn't say that, though.</p> <p>23 Q -- do you have -- no, no, no, I know it</p> <p>24 doesn't.</p> <p>25 A Oh.</p>
<p style="text-align: right;">Page 219</p> <p>1 parts, and I -- I like the way that I answered it.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Well, let me ask you this: My -- if</p> <p>4 Judge Wolfson, who is the judge presiding over</p> <p>5 this case, says to you, Dr. Diette, I've got a</p> <p>6 question for you -- this is in July -- do you have</p> <p>7 an opinion whether or not habitual use of talcum</p> <p>8 powder on the genital area may increase the risk</p> <p>9 for ovarian cancer, what are you going to tell</p> <p>10 her?</p> <p>11 MS. BROWN: Objection to the form of the</p> <p>12 question and to the yelling at the witness.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q I'm not yelling at you, Dr. Diette.</p> <p>15 MS. PARFITT: Everyone is saying I</p> <p>16 talk -- believe me, I'm not yelling at him. I'm</p> <p>17 not that disrespectful. Trust me, please.</p> <p>18 THE WITNESS: Okay. I don't think it</p> <p>19 does, but, you know, there's so many ways you</p> <p>20 could write this, which is why that it doesn't</p> <p>21 strike me as something to agree or disagree with.</p> <p>22 They could -- could have said "habitual use</p> <p>23 causes." They could have said that it does</p> <p>24 increase the risk.</p> <p>25 So, you know, those are very different</p>	<p style="text-align: right;">Page 221</p> <p>1 Q I'm representing -- you've already told</p> <p>2 me what you said about what's here.</p> <p>3 A I see.</p> <p>4 Q What I'm asking you is, do you have an</p> <p>5 opinion whether or not the habitual use of talcum</p> <p>6 powder -- powder on the genital area may increase</p> <p>7 the risk for ovarian cancer?</p> <p>8 A Not to quibble, but you just said does</p> <p>9 increase before that, and now it's may increase?</p> <p>10 Is it -- is it does increase --</p> <p>11 Q I'm going to do both, yeah.</p> <p>12 A Okay. Well, I think this is so watered</p> <p>13 down that it doesn't really say anything</p> <p>14 definitive when you say "may increase." If the</p> <p>15 question is about "does increase," I would say it</p> <p>16 does not increase the risk.</p> <p>17 Q Okay. And as worded, you feel that it's</p> <p>18 somewhat equivocal. Is that fair?</p> <p>19 MS. BROWN: Objection to the form of the</p> <p>20 question.</p> <p>21 THE WITNESS: Well, not the entire</p> <p>22 statement. I mean the evidence is not strong.</p> <p>23 Seems like a pretty -- a pretty potent part of the</p> <p>24 statement.</p> <p>25 BY MS. PARFITT:</p>

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<p style="text-align: right;">Page 222</p> <p>1 Q Okay. So you agree with "the evidence 2 is not strong." 3 And then what about the next part, "A 4 study at Harvard Medical School found that using 5 talc this way doubled the risk, but other studies 6 found no increased risk." Do you agree with that 7 statement? 8 MS. BROWN: Objection to the form of the 9 question. 10 THE WITNESS: It's -- I would say maybe. 11 And the reason is because they -- they haven't 12 cited what the Harvard study is. It -- I could 13 assume, but I might be wrong that maybe it's the 14 Cramer study from '82. Maybe it's not. So I 15 don't know. So if they're citing that, then -- 16 then that might well be a correct statement. And 17 it's certainly correct that other studies have 18 found no increased risk. 19 BY MS. PARFITT: 20 Q All right. So from your review of the 21 medical and scientific literature, you have seen 22 where scientists who look at the same scientific 23 and medical literature can arrive at different 24 opinions, correct? 25 MS. BROWN: Objection to the form of the</p>	<p style="text-align: right;">Page 224</p> <p>1 MS. BROWN: -- of the question, 2 misstates the document, and it's been asked and 3 answered. 4 THE WITNESS: I'd be careful a lot of 5 ways, right? I think it's -- it's easy to say 6 what, you know, Johns Hopkins is saying. I don't 7 know how well this represents Johns Hopkins as an 8 entity. I -- like I don't know who controls this 9 website. I don't know who the author was. I 10 don't know if it was -- you know, somebody who was 11 hired for the summer to create a website or 12 whether it's somebody who is a credible 13 researcher. 14 But I also know that these kinds of 15 things populate all kinds of different websites, 16 and they're not necessarily like a policy 17 statement, you know, of a university or a hospital 18 or an entity. 19 BY MS. PARFITT: 20 Q And I'll -- 21 A I would just be careful, I mean just in 22 terms of saying Johns Hopkins is saying this. 23 Q Well, I will represent to you, and you 24 can see for yourself, that the Sidney Kimmel 25 Comprehensive Center puts out this information.</p>
<p style="text-align: right;">Page 223</p> <p>1 question. 2 THE WITNESS: Are we talking about a 3 specific topic or just you -- in general, that 4 scientists can disagree with each other? 5 BY MS. PARFITT: 6 Q Scientists can disagree with each other. 7 MS. BROWN: Objection to the form. 8 THE WITNESS: I think in general, they 9 can disagree about all sorts of things. I don't 10 think there's a good reason to disagree about this 11 topic that we're talking about. 12 BY MS. PARFITT: 13 Q Well, in this particular sentence, Johns 14 Hopkins University is representing to consumers, 15 or anyone who wants to get onto the website, that 16 medical schools found -- that a study of the 17 Harvard Medical School found that using talc this 18 way doubled the risk, but other studies found no 19 increased risk. 20 A Yes. 21 Q Is it fair to say they're communicating 22 that there are science -- there's science out 23 there that goes both ways? 24 MS. BROWN: Objection to the form -- 25 MR. LOCKE: Objection.</p>	<p style="text-align: right;">Page 225</p> <p>1 Your institution. 2 MS. BROWN: Objection to the form of the 3 question, and misstates the document. 4 THE WITNESS: It's the same issue. 5 Right. I mean I know the Sidney Kimmel Cancer 6 Center, and I work there. It's -- but I don't 7 know what the source is of this information, I 8 don't know who's the author, and I don't know what 9 they expect it to represent in terms of a Johns 10 Hopkins, you know, point of view. 11 BY MS. PARFITT: 12 Q Did anyone over at the Sidney Kimmel 13 Comprehensive Cancer Center ever consult you with 14 regard to what language should be included on the 15 website with regard to risk factor information? 16 A No. 17 MS. BROWN: Objection to the form. 18 BY MS. PARFITT: 19 Q Okay. The second part, let's go on. If 20 you will, it starts with -- if you can read on 21 "Some," if you would read that, please. 22 A "Some researchers believe that talc may 23 be carcinogenic because it contains particles of 24 asbestos, a known carcinogen." 25 Q All right. And do you agree with that</p>

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<p>1 statement?</p> <p>2 MS. BROWN: Objection to the form.</p> <p>3 THE WITNESS: Well, I certainly agree</p> <p>4 that some researchers believe that, because we've</p> <p>5 seen it in plaintiffs' experts. So it's -- on its</p> <p>6 face, I think it's a -- a true -- true statement</p> <p>7 that there are people who believe that.</p> <p>8 And I think the part that asbestos is a</p> <p>9 known carcinogen is also something I agree with.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Okay. And then it goes on to say:</p> <p>12 "It's been shown that rates of ovarian cancer are</p> <p>13 higher than normal in women whose jobs expose them</p> <p>14 to asbestos."</p> <p>15 Do you agree with that statement?</p> <p>16 A So, you know, this language is -- is not</p> <p>17 great, right? It has been shown that, right. So</p> <p>18 we could look at, you know, any one of those</p> <p>19 studies that was done around World War II, for</p> <p>20 example, and if you looked at one that was</p> <p>21 positive, you could say it was shown that they</p> <p>22 were higher. I'm not sure whether the general</p> <p>23 proposition has been established, though.</p> <p>24 Q Okay.</p> <p>25 A If you guys are going to whisper, you're</p>	<p>1 out to the Food and Drug Administration to share</p> <p>2 your opinions with them?</p> <p>3 A No.</p> <p>4 Q All right. Other than counsel who has</p> <p>5 retained you to provide an expert -- a legal</p> <p>6 expert report, have you reached out to any</p> <p>7 scientific body to share your opinions?</p> <p>8 MS. BROWN: Objection to the form.</p> <p>9 THE WITNESS: No.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Okay. Have you reached out to any</p> <p>12 medical body to share your opinions?</p> <p>13 MS. BROWN: Objection to the form.</p> <p>14 THE WITNESS: No.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. Did you reach out to the Sidney</p> <p>17 Kimmel Comprehensive Cancer Center and the folks</p> <p>18 over there and share with them what your opinions</p> <p>19 are?</p> <p>20 A No.</p> <p>21 MS. BROWN: Asked and answered.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Do you know Dr. Merlo?</p> <p>24 A I do.</p> <p>25 Q He's a friend of yours, right?</p>
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<p>1 going to miss what I'm saying.</p> <p>2 Q No, I was -- I was just turned.</p> <p>3 A Okay.</p> <p>4 Q I heard what you said. Thank you.</p> <p>5 A All right.</p> <p>6 Q And fortunately, I have it right here in</p> <p>7 front of you too.</p> <p>8 A Okay, good. Good, good, good.</p> <p>9 Q Yeah, thank you. And I thought you had</p> <p>10 finished what you were saying because you finished</p> <p>11 "okay," so I thought --</p> <p>12 MS. BROWN: That's your "okay," Counsel.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q I'm sorry. I believe you finished. I'm</p> <p>15 not sure whether the general proposition has been</p> <p>16 established. So I thought that was the end --</p> <p>17 A That was the end --</p> <p>18 Q -- of your sentence.</p> <p>19 A Yeah.</p> <p>20 Q Right. Okay. All right.</p> <p>21 A Are we done with this one?</p> <p>22 Q For the time being, yeah. We may come</p> <p>23 back to that.</p> <p>24 Other than providing counsel with an</p> <p>25 expert report of your opinions, have you reached</p>	<p>1 A He is.</p> <p>2 Q Okay. And you're Facebook friends.</p> <p>3 A I'm friends with his wife. He and I</p> <p>4 might be also, but we're friends in -- in reality,</p> <p>5 not just on --</p> <p>6 Q Not just on Facebook.</p> <p>7 A Yeah.</p> <p>8 Q Is his wife a doctor?</p> <p>9 A She is not.</p> <p>10 Q Okay. Do you know Dr. April</p> <p>11 Zambelli-Weiner?</p> <p>12 A I do.</p> <p>13 Q Okay. You have worked with her in the</p> <p>14 past, correct?</p> <p>15 A Really briefly, way back when.</p> <p>16 Q Okay. Do you consider her -- do you</p> <p>17 know she's an epidemiologist, correct?</p> <p>18 A I think I know that.</p> <p>19 Q Okay. Do you consider her an</p> <p>20 epidemiologist with expertise and well received in</p> <p>21 the medical comm- -- and scientific community?</p> <p>22 MS. BROWN: Objection. Lacks</p> <p>23 foundation, calls for speculation.</p> <p>24 THE WITNESS: So I don't know much</p> <p>25 about -- about her lately. I think the last time</p>

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<p style="text-align: right;">Page 230</p> <p>1 that I saw her was when she was still training at 2 Hopkins. And so there's a couple of decades that 3 have gone by. So I -- so I honestly have no idea 4 what her reputation is at this point. 5 BY MS. PARFITT: 6 Q Okay. Did you work with her? 7 A Sort of. Like not -- we were -- we were 8 both involved in a research project, but we 9 weren't both involved in the same part of the 10 project. So I -- it's -- to say that we worked 11 together, it's -- it's a little bit vague in a way 12 about whether we did. We traveled together for 13 one particular research program we were a part of. 14 But -- 15 Q Okay. 16 A Like I don't think we published 17 together. I don't think. 18 Q Do you think of her as a good scientist? 19 MS. BROWN: Objection to the form of the 20 question, calls for speculation. 21 THE WITNESS: I -- I honestly don't know 22 what she's -- what she's up to. I mean it's 23 literally been a couple of decades. 24 BY MS. PARFITT: 25 Q Sure. Well, when you did know her back</p>	<p style="text-align: right;">Page 232</p> <p>1 appear and give testimony, correct? 2 A Correct. 3 MS. BROWN: Form. 4 BY MS. PARFITT: 5 Q Right. So no one inquired as to what 6 your opinions were on this topic; is that correct? 7 MS. BROWN: Asked and answered. 8 THE WITNESS: That is correct. 9 BY MS. PARFITT: 10 Q Okay. I'll represent to you that at the 11 hearing, both consumer and industry were invited 12 to attend. 13 Are you aware that Dr. McTiernan, who is 14 an expert in this case, was one of those 15 individuals that was invited to attend? 16 MR. LOCKE: Objection. 17 MS. BROWN: Objection. Lacks 18 foundation. 19 THE WITNESS: I don't know. 20 BY MS. PARFITT: 21 Q Okay. You've read her expert report, 22 correct? 23 A I did. 24 Q And you understand that she was one of 25 the coinvestigators with the WHI study?</p>
<p style="text-align: right;">Page 231</p> <p>1 a couple of decades ago, did you consider her a 2 good scientist? 3 MS. BROWN: Objection to the form, 4 vague, calls for speculation. 5 THE WITNESS: I wouldn't say that I know 6 that she wasn't, but I really wasn't very familiar 7 with what her work was. 8 BY MS. PARFITT: 9 Q Her work. Okay. That's fair enough. 10 Okay. Alrighty. Let's set this aside. 11 Dr. Diette, are you aware that just last 12 month, and I believe it was March 12th, the House 13 Committee on Oversight and Reform, Committee on 14 Economic and Consumer Policy conducted a hearing 15 about the public health risk of carcinogens in 16 talcum powder products and other consumer 17 products? Were you aware of that? 18 MR. LOCKE: Objection. 19 MS. BROWN: Objection to the form. 20 THE WITNESS: I saw that -- a question 21 about that in one of the deposition transcripts 22 that I -- that I read. I don't remember which 23 one. But that's my only awareness of that. 24 BY MS. PARFITT: 25 Q Okay. So no one requested that you</p>	<p style="text-align: right;">Page 233</p> <p>1 MS. BROWN: Objection to the form. 2 BY MS. PARFITT: 3 Q One of the cohorts that you rely on. 4 MS. BROWN: Foundation, speculation. 5 THE WITNESS: That's what I understand. 6 BY MS. PARFITT: 7 Q Okay. When you were writing your expert 8 report and researching the cohort studies, did you 9 ever reach out to Dr. McTiernan to consult with 10 her with regard to her thoughts and opinions about 11 that particular cohort study? 12 MS. BROWN: Objection to the form. 13 Which study? 14 MS. PARFITT: I said the WHI study. 15 MS. BROWN: It's not in your question. 16 THE WITNESS: Assuming the WHI study, I 17 did not. 18 BY MS. PARFITT: 19 Q Okay. Dr. McTiernan testified at that 20 hearing, and her testimony went uncontroverted, 21 that there was a statistically significant 22 increased risk of 22 to 31 percent of developing 23 ovarian cancer from genital use of talcum powder 24 products. 25 Do you agree or disagree with that?</p>

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<p style="text-align: right;">Page 234</p> <p>1 MR. LOCKE: Objection.</p> <p>2 MS. BROWN: Objection. This lacks</p> <p>3 foundation. Counsel, are you giving him a</p> <p>4 hypothetical? Or if not, are you going to give</p> <p>5 him something that would support the statements</p> <p>6 that you're making on the record?</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Assume that Dr. McTiernan testified</p> <p>9 before the subcommittee who was investigating the</p> <p>10 safety of talcum powder products, that</p> <p>11 Dr. McTiernan testified that there was scientific</p> <p>12 evidence that women who used talcum powder</p> <p>13 products have a statistically significant</p> <p>14 increased risk of 22 to 31 percent of developing</p> <p>15 ovarian cancer.</p> <p>16 A So, first of all --</p> <p>17 MS. BROWN: Wait, wait. What's the</p> <p>18 question?</p> <p>19 BY MS. PARFITT:</p> <p>20 Q And I should add developing epithelial</p> <p>21 ovarian cancer having used talcum powder products.</p> <p>22 MS. BROWN: What's the question? You</p> <p>23 just gave an assumption.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Do you --</p>	<p style="text-align: right;">Page 236</p> <p>1 March 12th, 2019.</p> <p>2 Do you see that?</p> <p>3 A I see it.</p> <p>4 Q Okay. If I can direct your attention</p> <p>5 to -- and I'll represent that this was a statement</p> <p>6 that she submitted prior to the hearing, and</p> <p>7 specifically -- I can put it on the ELMO here.</p> <p>8 Let's go down to the third full paragraph.</p> <p>9 Do you see that, it starts</p> <p>10 "Summarizing"?</p> <p>11 A Yes.</p> <p>12 Q Okay. And it states: "Summarizing data</p> <p>13 from all of the published studies consistently</p> <p>14 shows that women who had ever used talcum powder</p> <p>15 products in the genital area had a statistically</p> <p>16 significant 22 to 31 percent increased risk of</p> <p>17 developing epithelial ovarian cancer compared with</p> <p>18 women who had never used them. Evidence suggests</p> <p>19 that these associations hold across diverse race</p> <p>20 and ethnic groups."</p> <p>21 Did I read that correctly?</p> <p>22 A You did.</p> <p>23 Q All right. Do you agree with that</p> <p>24 statement?</p> <p>25 MS. BROWN: Objection to the form.</p>
<p style="text-align: right;">Page 235</p> <p>1 MS. PARFITT: I just was finishing.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q But do you agree with her statement</p> <p>4 before Congress?</p> <p>5 MS. BROWN: Objection to the form.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 MS. BROWN: Incomplete hypothetical,</p> <p>8 lacks foundation, calls for speculation.</p> <p>9 THE WITNESS: So I don't know what she</p> <p>10 said -- and I know you're asking me to assume what</p> <p>11 she said -- I don't know what else she said about</p> <p>12 it, so how the -- how that's framed -- it sounds</p> <p>13 compatible generally with what her report had at</p> <p>14 least one sentence about.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. Let me show you what we'll have</p> <p>17 marked as Exhibit 13.</p> <p>18 (Diette Exhibit No. 13 was marked</p> <p>19 for identification.)</p> <p>20 BY MS. PARFITT:</p> <p>21 Q And I'll represent to you that this</p> <p>22 is the statement of Ann McTiernan that was</p> <p>23 prepared for the Subcommittee on Economic and</p> <p>24 Consumer Policy on "Examining the Public Health</p> <p>25 Risks of Carcinogens in Consumer Products" dated</p>	<p style="text-align: right;">Page 237</p> <p>1 THE WITNESS: Well, I think this is</p> <p>2 compatible with what, you know, her report and her</p> <p>3 testimony has been generally. I think it's --</p> <p>4 it's -- unfortunately, it's not very balanced,</p> <p>5 right. I mean she -- she's leaving out an awful</p> <p>6 lot of information here and -- and really</p> <p>7 referring just to one narrow slice of the evidence</p> <p>8 that she's -- that she's citing here.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q Okay. What did she leave out, Doctor?</p> <p>11 A I'm sorry?</p> <p>12 Q What is she leaving out?</p> <p>13 A Well, saying that -- that "data from all</p> <p>14 the published studies consistently shows that</p> <p>15 women who had ever used talcum powder products in</p> <p>16 the genital area had a statistically significant</p> <p>17 22 to 31 percent increased risk," and I won't</p> <p>18 finish the rest, but, you know, of developing</p> <p>19 ovarian cancer.</p> <p>20 So, you know, they don't all have a</p> <p>21 statistically significant increase, and she's</p> <p>22 leaving out information that would run counter to</p> <p>23 that also, including I think -- let me just see</p> <p>24 what she cites.</p> <p>25 She cites Berge and Penninkilampi and</p>

60 (Pages 234 to 237)

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<p style="text-align: right;">Page 238</p> <p>1 Terry, but there's other information in there, 2 like from Berge, for example, you know, who points 3 out that there's no risk seen in the cohort 4 studies. So I think if this were balanced, that 5 she would -- she would have more information than 6 just that particular statement. 7 Q Okay. And we'll talk a little bit more 8 about the -- the cohorts in just -- just a moment. 9 Okay. What was the methodology you 10 employed in order to present the opinions and 11 bases for opinions in your report? 12 A So generally, I tried to identify all of 13 the relevant epidemiologic studies -- is that what 14 you're -- you're asking? 15 Q That is? 16 A Okay. 17 Q That is. 18 A And so I tried to find them in an 19 iterative way, you know, meaning that there were 20 meta-analyses that had many of them listed. I did 21 some searches of their own reference lists to look 22 for others. I did searches, you know, using 23 web-based, you know, tools to find other -- other 24 studies, and tried to get what I thought was a 25 pretty comprehensive group of all the</p>	<p style="text-align: right;">Page 240</p> <p>1 search terms that you used in order to do your 2 literature review? 3 A I didn't -- I didn't write them down, 4 but it -- you know, this didn't start as like a -- 5 like a -- like there's been some searches that 6 I've been involved in where, you know, somebody 7 might commission a review of a particular topic, 8 and you have to figure out what those search terms 9 are. 10 In this case, there's a really good head 11 start because there's meta-analyses done and 12 there's some other -- some other papers. And so 13 what I tried to use was the words that the authors 14 used, you know, assuming that they would then link 15 up and find the other -- other articles. 16 So -- so like "ovarian cancer," "talc," 17 "talcum powder," probably some -- you know, some 18 words like "risk" and "cause" and -- I think for 19 that part of it that was -- that was kind of the 20 bulk of it. There may have been other terms that 21 came up in some of the -- some of the articles 22 that I would search for also, but that -- that was 23 the main ones. 24 Q Did you search for the word "cancer"? 25 A Oh, well, "ovarian cancer."</p>
<p style="text-align: right;">Page 239</p> <p>1 epidemiologic studies. 2 And then I also tried to read other 3 things, you know, IARC monographs, other -- like 4 reports from like American College of Obstetrics 5 and Gynecology, and -- and get a sense of how some 6 of the information was being interpreted by 7 other -- other bodies. 8 And -- and then ultimately looked at 9 criteria that people recognize as useful for 10 assessing causation, which are labeled sometimes 11 Bradford Hill considerations, and then other 12 things too. 13 So besides that, then, you know, looking 14 at the quality of the studies in some cases. So, 15 for example, were there valid measures of -- of 16 exposure that were used, was there evidence for 17 confounding and bias, and so forth. 18 Q All right. 19 A Meaning especially those latters 20 aren't -- those latter factors aren't part of 21 Bradford Hill. Like he doesn't talk about, you 22 know, bias and confounding and validity of the 23 measures and so forth. So there's more to looking 24 at it than just Bradford Hill. 25 Q Okay. So what was -- what were the</p>	<p style="text-align: right;">Page 241</p> <p>1 Q Okay. Did you search for the word 2 "asbestos"? 3 A I did, but differently -- so I did sort 4 of a separate search for that, which was "asbestos 5 and ovarian cancer." Same approach, but -- but 6 different -- I thought we were just talking about 7 the talcum powder at the moment. 8 But separately, I did a search for 9 "asbestos and -- and ovarian cancer." And -- and 10 just like for this issue of talcum powder, there 11 was a good head start from -- from IARC, at least 12 having identified several -- several key studies, 13 and then looked for more because there were 14 obviously some that they didn't cite or that 15 weren't available to them at the time that they 16 did their -- their review. 17 Q Did you search for the word 18 "inflammation"? 19 A I did, for -- part of the searches was 20 for inflammation. 21 Q Okay. 22 A I should say also -- I mean there's more 23 to it if you want, just a little bit more. 24 Q No. Let me ask you a question first. 25 A Okay.</p>

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<p>1 Q There's no question pending.</p> <p>2 I assume you did a literature search</p> <p>3 back in the early part of 2017 when you were first</p> <p>4 retained, correct?</p> <p>5 A Correct.</p> <p>6 Q All right. So did you update that</p> <p>7 literature search?</p> <p>8 A Oh, yeah.</p> <p>9 Q Okay. Did you keep -- do you keep some</p> <p>10 kind of recordation of material you had before and</p> <p>11 then what material you're looking at now for</p> <p>12 purposes of this most recent report?</p> <p>13 A No, I mean it's not sorted by -- by when</p> <p>14 I found it.</p> <p>15 Q All right. You represented, at least in</p> <p>16 your report, that you looked at the databases</p> <p>17 Medline and Google.</p> <p>18 Did you use any other databases for your</p> <p>19 research?</p> <p>20 A Well, scholar -- Google Scholar as</p> <p>21 opposed to just plain Google and then main Google</p> <p>22 itself. I don't remember if I used any others.</p> <p>23 Q Okay. Where in your report do you share</p> <p>24 your systematic review and collection of the</p> <p>25 various literature that formed the bases of your</p>	<p>1 A Some --</p> <p>2 MS. BROWN: Objection to the form.</p> <p>3 THE WITNESS: Some of it.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay. And how did you select the</p> <p>6 case -- the cases that became part of your list of</p> <p>7 cases on page 13 and 14 of your report?</p> <p>8 A What does "cases" mean?</p> <p>9 Q Studies. You have them listed on</p> <p>10 page 13, and it carries over to page 14.</p> <p>11 A It's -- the way I describe it, I don't</p> <p>12 think I got to finish answering the question about</p> <p>13 the -- the rest of the methodology. You'd have to</p> <p>14 turn over to page 6, and in the section called</p> <p>15 "Review of Epidemiology Data," there's a</p> <p>16 description of what I just told you verbally just</p> <p>17 a moment ago, which is talking about MedLine and</p> <p>18 Google Scholar, and reviewed the reference list of</p> <p>19 the individual studies and the meta-analyses to</p> <p>20 assemble a complete list of studies, and then I --</p> <p>21 it goes on. That's not the whole paragraph</p> <p>22 obviously, but that's the -- that's the general</p> <p>23 method of how I found them.</p> <p>24 Q Okay. And what process did you go</p> <p>25 through to select or deselect certain pieces of</p>
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<p>1 opinion?</p> <p>2 A I didn't write that part, I don't think,</p> <p>3 but it -- I do talk about the -- the methodology</p> <p>4 in general.</p> <p>5 Q Okay. Well, you talk about the</p> <p>6 methodology on page -- I believe it's page 4, and</p> <p>7 there's about two paragraphs there, and then on</p> <p>8 the top of page 5, where there's just two full</p> <p>9 paragraphs.</p> <p>10 So my question is, where do you -- is</p> <p>11 there anywhere else in your report that you set</p> <p>12 forth your methodology --</p> <p>13 A Yeah.</p> <p>14 Q -- employed in order to --</p> <p>15 A Sure, other places --</p> <p>16 Q -- form the basis for your opinions?</p> <p>17 A Sorry, I didn't mean to interrupt.</p> <p>18 Q No, and what I'm saying --</p> <p>19 A Were you done?</p> <p>20 Q -- you have a methodology section --</p> <p>21 let's start over.</p> <p>22 You have a methodology section of your</p> <p>23 report. Is it fair that that is where you set</p> <p>24 forth the methodology that you employ in this</p> <p>25 case?</p>	<p>1 literature that you reviewed?</p> <p>2 A Well, I -- I included all of the ones</p> <p>3 that I could find. I mean we're talking about the</p> <p>4 epidemiologic studies.</p> <p>5 Q We are. We are indeed, yeah.</p> <p>6 A So like in terms of the cohort studies,</p> <p>7 there's only three I could find. There's more</p> <p>8 than three publications that pertain to the three,</p> <p>9 but I included all three, and I included all the</p> <p>10 publications I could find on the topic.</p> <p>11 But the case-control study, a similar</p> <p>12 approach, although there's a little bit of</p> <p>13 confusion with the case controls because there's</p> <p>14 overlap. There is a redundant publication where</p> <p>15 some authors are presenting the same data twice,</p> <p>16 and it's not entirely clear how to unravel them.</p> <p>17 So I just tried to include as many of those as I</p> <p>18 could that looked like distinct studies, and I</p> <p>19 tried to make sure I had the -- you know, the vast</p> <p>20 majority of what was being considered in the</p> <p>21 meta-analysis as well.</p> <p>22 Q I think where I'm going is, where do</p> <p>23 you -- where do you tell the -- the reader what</p> <p>24 your inclusion criteria was for selecting studies?</p> <p>25 MS. BROWN: Objection to the form.</p>

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<p style="text-align: right;">Page 246</p> <p>1 THE WITNESS: I tried to get them all. 2 I wasn't trying to exclude any studies. 3 BY MS. PARFITT: 4 Q So every -- so may I assume from that 5 statement that all of the literature that you've 6 listed on page 13 and 14 in the cohort studies and 7 the meta-analysis is the entire body of literature 8 that you reviewed? 9 A Of course not. 10 MS. BROWN: Objection to the form. 11 THE WITNESS: No, no, what -- well, I 12 guess, if you could, please be very precise what 13 you're asking. 14 To me what I think we're talking about 15 is the case-control studies and the cohort 16 studies, and so I tried to identify every single 17 one of them. So I didn't have an exclusion 18 criteria to say I was going to ignore this one 19 because it wasn't supportive of my view or 20 something like that. I included them all. 21 I searched for clinical trials, but 22 there weren't any. So that was -- that was an 23 issue as well. 24 BY MS. PARFITT: 25 Q Were there any studies that you chose</p>	<p style="text-align: right;">Page 248</p> <p>1 of the risk -- risk estimates, not of the number 2 of cases. 3 BY MS. PARFITT: 4 Q Correct. So where on this page 13 or 14 5 do you tell the reader how many ovarian cancer 6 cases were part of that study? 7 MS. BROWN: Objection to the form. 8 THE WITNESS: It's not on there. 9 BY MS. PARFITT: 10 Q Okay. Where on your list of cases, 13 11 and 14, do you tell the reader the number of 12 controls that were involved in that study? 13 A I didn't -- I didn't list every single 14 thing like that on here. 15 Q You didn't list it in your report 16 either, correct? 17 MS. BROWN: Objection to the form. 18 THE WITNESS: Well, this is the report. 19 BY MS. PARFITT: 20 Q Well, you didn't list it anywhere else 21 other -- that information is not contained in your 22 report. Is that fair? 23 MS. BROWN: Objection to the form. 24 MR. LOCKE: Objection. 25 THE WITNESS: The sample size?</p>
<p style="text-align: right;">Page 247</p> <p>1 not to include on your list of 13 and 14 that you 2 had actually reviewed during the course of your 3 study? 4 A And we're talking about case-control 5 studies and cohorts. 6 Q Correct. 7 A I didn't -- wait a minute. I didn't 8 deliberately not include any of them. I tried to 9 include every single one, with that exception 10 being -- and I don't remember which ones were 11 which, but there were a couple that were 12 redundant. You know, the -- the authors of these 13 haven't in every case been careful about reporting 14 findings that are unique. 15 Q Okay. Focusing now, if I may, on your 16 chart, page 13 and 14 of the case-control studies. 17 Do you have that in front of you? 18 A Almost. 19 Q Okay. 20 A I do. 21 Q All right. Where in this document, 22 page 13 and 14, do you identify the number of 23 ovarian cases that formed the bases of the study? 24 MS. BROWN: Objection to the form. 25 THE WITNESS: This is the list of the --</p>	<p style="text-align: right;">Page 249</p> <p>1 BY MS. PARFITT: 2 Q The sample size is not information that 3 you contained -- that you included in your report, 4 correct? 5 A I did not. 6 MS. BROWN: Same objection. 7 BY MS. PARFITT: 8 Q Okay. Where in your report do you tell 9 the reader the country from where these studies 10 came from? 11 MS. BROWN: Objection to the form. 12 THE WITNESS: I don't list that. 13 BY MS. PARFITT: 14 Q Okay. Where do you tell the reader what 15 the mean age of the participants in this study 16 were? 17 MS. BROWN: Same objection. 18 THE WITNESS: And same answer, I 19 don't -- I don't list that either. 20 BY MS. PARFITT: 21 Q Where in your report do you tell the 22 reader the number of adjusted variables per study 23 that were considered? 24 MS. BROWN: Objection to the form. 25 THE WITNESS: I didn't -- I didn't</p>

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<p style="text-align: right;">Page 250</p> <p>1 capture that here. 2 BY MS. PARFITT: 3 Q Okay. And where in your report do you 4 tell the reader the type of ovarian cancer that 5 the women suffered? 6 MS. BROWN: Objection to the form. 7 THE WITNESS: That's not listed on -- on 8 this table either. 9 BY MS. PARFITT: 10 Q Did you create this table yourself or 11 did you have assistance? 12 A So, actually, I made this initially, and 13 there might have been a couple that filtered in 14 after I started to create it where -- you know, 15 where I had an assistant, you know, plug in a 16 different study. 17 Q Where in your report do you tell the 18 reader if you applied a scoring system to the data 19 and the studies that you reviewed? 20 A That wasn't -- 21 MS. BROWN: Objection. Lacks 22 foundation. 23 THE WITNESS: That wasn't my approach. 24 BY MS. PARFITT: 25 Q Okay. We'll talk about that in a</p>	<p style="text-align: right;">Page 252</p> <p>1 Q What specific, if any, in vitro studies 2 did you consider for purposes of your opinion? 3 A So I -- are you good? 4 Q Yeah, thank you. 5 A Okay. So I -- I don't know if you're 6 including some animal studies as in vitro studies 7 or whether you just mean sort of like ones that 8 are -- that are cell-based or in a dish. 9 Q Well, there's a difference, isn't there? 10 A There should be, yeah, but I just -- 11 since you're asking the question, I don't know 12 you, and so I -- I just want to be clear. 13 Q No, I'm -- I'm cognizant of the 14 difference between in vivo and in vitro, so what 15 I -- what I would ask you is what in vitro studies 16 did you consider for purposes of your analysis? 17 A Yeah, I looked at some. I think the 18 ones that were cited by IARC I looked at. I don't 19 remember the full list of ones -- which ones I may 20 have listed, if any, that -- that I looked at. 21 But that wasn't really my main -- my main purpose 22 in looking at the epidemiology, which was to -- 23 was to look at in vitro studies. 24 Q Okay. Was part of your analysis -- or 25 did part of your analysis include looking at</p>
<p style="text-align: right;">Page 251</p> <p>1 minute. Appreciate that. 2 Did you exercise any independent 3 judgment in determining what cases to include on 4 this chart of case-control studies on 13 and 14? 5 MS. BROWN: Objection. Asked and 6 answered. 7 THE WITNESS: I tried to be inclusive. 8 BY MS. PARFITT: 9 Q Being inclusive -- did being inclusive 10 require you to exercise professional judgment with 11 regard to selection of the cases that you reviewed 12 and included for purposes of your analysis? 13 A So, mostly, yes. What I would say is I 14 was trying to understand what the universe was of 15 case controls that were being listed in the 16 meta-analyses, what the case controls were that 17 were informing the opinions of the plaintiffs' 18 experts. And so I didn't want to have some 19 arbitrary rule for saying one shouldn't be in 20 here. I wanted to look at them all. And so my 21 goal was actually to include them all, and not 22 deselect some because I thought that there was a 23 quality issue with them. 24 (Brief interruption.) 25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 253</p> <p>1 in vivo studies? 2 A So I looked at -- at a bunch of the 3 different animal studies that were cited, cited in 4 some of the other documents. 5 Q Which ones? 6 A So I don't remember the author names. I 7 mean, there were -- there were studies of, you 8 know, rats, rabbits, primates. I can't remember 9 if there were mouse -- there were mouse studies as 10 well. 11 So whatever that list is that was in 12 IARC that they had considered at that point, and 13 then I think I found a couple more. 14 Q What, if any, information did you glean 15 from your review of the in vitro and in vivo 16 studies that formed the basis of your study 17 report? 18 A Well, mostly -- so to -- to think about 19 how -- for me as an epidemiologist, and not as a 20 cancer biologist or molecular biologist, I wanted 21 to just understand generally how some of the other 22 entities were wielding that information, right. 23 So that -- like I wasn't about to become a cancer 24 biologist in reading these things or understand 25 whether their methods were appropriate or not, but</p>

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<p style="text-align: right;">Page 254</p> <p>1 I did want to understand some of their</p> <p>2 underpinnings.</p> <p>3 Q Okay.</p> <p>4 A And just so, for example, right, so</p> <p>5 there's the -- the studies on migration, for</p> <p>6 example. I thought it was important to look at</p> <p>7 those and see what kind of animals, for example,</p> <p>8 had what kind of particles either put into their</p> <p>9 vaginas or put into their uterus, or whatever it</p> <p>10 was, so I could understand what the -- what the</p> <p>11 story was there.</p> <p>12 Q Okay. Do animals have vaginas?</p> <p>13 A Some do, yeah.</p> <p>14 Q You -- you indicated you're not a cancer</p> <p>15 specialist. Would you defer to -- on topics</p> <p>16 involving those issues to a cancer biologist?</p> <p>17 MS. BROWN: Objection to the form of the</p> <p>18 question.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q And let me clean it up because I think I</p> <p>21 left that off. You are not a cancer biologist,</p> <p>22 correct?</p> <p>23 A Correct.</p> <p>24 Q All right. So would you defer questions</p> <p>25 in that wheelhouse to someone who is a cancer</p>	<p style="text-align: right;">Page 256</p> <p>1 MS. BROWN: What report is --</p> <p>2 MS. PARFITT: Saed.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q Just give me a moment, Doctor.</p> <p>5 If you turn your attention to page 42.</p> <p>6 A Mm-hmm.</p> <p>7 Q At the bottom.</p> <p>8 A Okay.</p> <p>9 Q "I leave a detailed assessment of</p> <p>10 Dr. Saed's efforts to other experts. I did review</p> <p>11 Dr. Saed's report and his two depositions and was</p> <p>12 struck by the irregularities in his study, which</p> <p>13 render his results highly questionable."</p> <p>14 So are you or are you not deferring with</p> <p>15 regard to opinions concerning what Dr. Saed had to</p> <p>16 say?</p> <p>17 MS. BROWN: Objection. Misstates the</p> <p>18 expert report and the opinion.</p> <p>19 THE WITNESS: I -- I meant to be</p> <p>20 somewhat nuanced here, right, which is that -- you</p> <p>21 know, it's possible for me to read things and</p> <p>22 understand that there might be some issues with</p> <p>23 what he's done. I -- I'm not going to be the</p> <p>24 person to critique the biologic aspects of his</p> <p>25 work, though.</p>
<p style="text-align: right;">Page 255</p> <p>1 biologist?</p> <p>2 MS. BROWN: Same objection.</p> <p>3 THE WITNESS: So I mostly don't think</p> <p>4 about deferring my opinions to other -- other</p> <p>5 people's categorically. You know, so that I think</p> <p>6 if there were somebody that was a cancer biologist</p> <p>7 and they had an opinion that seemed credible, I</p> <p>8 would take it into account. But to the extent</p> <p>9 that I needed to understand something, I would</p> <p>10 still rely on my own -- my own background and</p> <p>11 knowledge.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q All right. You're not a -- a molecular</p> <p>14 specialist, correct?</p> <p>15 MS. BROWN: Objection.</p> <p>16 THE WITNESS: Not a molecular biologist.</p> <p>17 BY MS. PARFITT:</p> <p>18 Q Okay. I believe you stated in your</p> <p>19 report that you were deferring to other experts in</p> <p>20 this case as it pertains to the opinions that</p> <p>21 Dr. Saed has given; is that correct?</p> <p>22 MS. BROWN: Objection to the form.</p> <p>23 Counsel, is there a part of the report you're</p> <p>24 referring to?</p> <p>25 MS. PARFITT: Mm-hmm, there is.</p>	<p style="text-align: right;">Page 257</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Okay. Fair enough. In fact, let me ask</p> <p>3 you, have you read the published scientific</p> <p>4 article by Dr. Saed?</p> <p>5 A Not yet.</p> <p>6 Q Okay. Do you have any plans to do that?</p> <p>7 A I might. I might, because I was just --</p> <p>8 I was curious because I saw some of the -- like</p> <p>9 the expert reports that came in after I wrote my</p> <p>10 report, and there were things that just kind of</p> <p>11 struck me that would be worth trying to sort</p> <p>12 through, like whether he had changed like 48 to 36</p> <p>13 or -- yeah, 48 hours to 72 hours, whatever it was,</p> <p>14 that there were like some tables apparently that</p> <p>15 were the same as an original paper, that the only</p> <p>16 change was like the numbers on them. And so just</p> <p>17 to sort of understand the quality issues related</p> <p>18 to the study, I thought I might take a look at it.</p> <p>19 Q All right. But prior to preparing your</p> <p>20 expert report, and, frankly, this deposition</p> <p>21 today, you have not read either Dr. Saed's -- you</p> <p>22 have not read Dr. Saed's most current peer-</p> <p>23 reviewed paper, correct?</p> <p>24 A True for both time periods. I don't</p> <p>25 think it was published or available to me before I</p>

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<p style="text-align: right;">Page 258</p> <p>1 did the report, but I could be wrong.</p> <p>2 Q Well, it's available now, isn't it?</p> <p>3 A That's what I've heard.</p> <p>4 MS. BROWN: Objection to the form.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q But you've not seen it.</p> <p>7 A No. I just -- I mean like -- I mean</p> <p>8 it -- sorry, it's the way I think. It sounds like</p> <p>9 two different time periods. One was --</p> <p>10 Q No.</p> <p>11 A -- before the report and one was between</p> <p>12 then and now.</p> <p>13 Q No, my question goes --</p> <p>14 MS. BROWN: Wait, he's finishing. Let</p> <p>15 him finish.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q My question -- are you done?</p> <p>18 A I'm good.</p> <p>19 Q My question really goes to, is it fair</p> <p>20 to say that you have not read Dr. Saed's published</p> <p>21 peer-reviewed article at the time of your</p> <p>22 deposition?</p> <p>23 A That is correct.</p> <p>24 THE WITNESS: Sorry.</p> <p>25 MS. BROWN: That's all right.</p>	<p style="text-align: right;">Page 260</p> <p>1 think, but I've certainly read other -- I mean</p> <p>2 others that aren't on either of those topics.</p> <p>3 Q Would you agree -- would you agree that</p> <p>4 IARC is a well-respected scientific organization?</p> <p>5 MS. BROWN: Object -- I'm sorry. I</p> <p>6 didn't hear the question.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Would you agree that IARC is a well-</p> <p>9 respected scientific organization?</p> <p>10 MS. BROWN: Objection to the form.</p> <p>11 THE WITNESS: It's -- it's hard for me</p> <p>12 to characterize whole organizations, you know, in</p> <p>13 terms of whether they're well respected or by whom</p> <p>14 or when, but generally speaking, you know, they --</p> <p>15 they do produce some -- some credible documents.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q They do produce some credible documents.</p> <p>18 It's -- IARC is part of the World Health</p> <p>19 Organization, correct?</p> <p>20 A It is.</p> <p>21 Q Okay. And when IARC has its meetings to</p> <p>22 discuss classification of carcinogens, it invites</p> <p>23 world-renowned experts for whatever area and</p> <p>24 specialty is being discussed. Is that fair?</p> <p>25 MS. BROWN: Objection to the form.</p>
<p style="text-align: right;">Page 259</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Okay. Now, you've mentioned IARC a</p> <p>3 couple of times during the course of your</p> <p>4 testimony.</p> <p>5 Have you rereviewed the IARC</p> <p>6 monographs -- or the IARC monogram that was</p> <p>7 published in 2010 on silica?</p> <p>8 MS. BROWN: The monograph?</p> <p>9 MS. PARFITT: The monograph. Monograph.</p> <p>10 MS. BROWN: Monograph on talc?</p> <p>11 MS. PARFITT: On talc, mm-hmm.</p> <p>12 THE WITNESS: Did you just say silica or</p> <p>13 no?</p> <p>14 BY MS. PARFITT:</p> <p>15 Q I did say silica. I meant talc.</p> <p>16 A You meant talc. Yeah, I've read the</p> <p>17 talc one.</p> <p>18 Q You've read the talc one. Have you read</p> <p>19 the 2012 monograph, the one 100C, have you seen</p> <p>20 that?</p> <p>21 A I have.</p> <p>22 Q Okay. Have you read any other</p> <p>23 monographs on talc or asbestos?</p> <p>24 A I've read earlier ones on asbestos. I</p> <p>25 don't know of any other ones on talc, I don't</p>	<p style="text-align: right;">Page 261</p> <p>1 MR. LOCKE: Objection.</p> <p>2 MS. BROWN: Calls for speculation.</p> <p>3 THE WITNESS: I don't know their</p> <p>4 selection process, but they -- but they certainly</p> <p>5 invite -- invite people to attend.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Okay. Have you ever been invited to</p> <p>8 attend an IARC --</p> <p>9 A I have not.</p> <p>10 Q -- working group?</p> <p>11 A No.</p> <p>12 Q Okay. Did IARC invite you to attend</p> <p>13 their working group back in 2006 when they were</p> <p>14 deliberating on the issue of talcum -- talc</p> <p>15 products?</p> <p>16 MS. BROWN: Objection. Same question,</p> <p>17 asked and answered.</p> <p>18 THE WITNESS: She's right, but -- but</p> <p>19 no.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Okay. Did IARC ever invite you to</p> <p>22 attend and share your opinions when they had their</p> <p>23 asbestos meetings?</p> <p>24 MS. BROWN: Same objection.</p> <p>25 THE WITNESS: No.</p>

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<p style="text-align: right;">Page 262</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Do you know what the NTP is?</p> <p>3 A It's like the National Toxicological</p> <p>4 Program.</p> <p>5 Q Okay. Has the National Toxicological</p> <p>6 Program ever asked you to do research for them on</p> <p>7 talcum powder products?</p> <p>8 A No.</p> <p>9 Q Has the National Toxicology Program ever</p> <p>10 asked that you do research with them on asbestos?</p> <p>11 A No.</p> <p>12 Q Have you ever submitted any research to</p> <p>13 the NTP on anything?</p> <p>14 A No.</p> <p>15 Q Have you ever submitted any research to</p> <p>16 IARC on anything?</p> <p>17 A No.</p> <p>18 Q What is a risk factor?</p> <p>19 MS. BROWN: Objection to the form.</p> <p>20 THE WITNESS: Are we talking about like</p> <p>21 an epidemiologic definition?</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Just generally, what's a risk factor?</p> <p>24 MS. BROWN: Objection.</p> <p>25 THE WITNESS: Well, I don't -- you said</p>	<p style="text-align: right;">Page 264</p> <p>1 Q For instance, if -- is talcum powder a</p> <p>2 modifiable behavior -- the use of talcum powder a</p> <p>3 modifiable behavior?</p> <p>4 MS. BROWN: Objection. Misstates his</p> <p>5 prior testimony.</p> <p>6 THE WITNESS: So it -- it should be,</p> <p>7 yeah.</p> <p>8 BY MS. PARFITT:</p> <p>9 Q Okay. Now, Dr. Diette, your paper or</p> <p>10 your expert report was signed and executed by you</p> <p>11 on February 25th, 2019.</p> <p>12 A Correct.</p> <p>13 Q Okay. When did you actually finish the</p> <p>14 paper, the report?</p> <p>15 A Oh, I think about then. I mean --</p> <p>16 Q About then?</p> <p>17 A I think around then. I mean it's -- I</p> <p>18 don't know whether it was the day before or the --</p> <p>19 or that actual day, but -- but right around then.</p> <p>20 Q Okay. Are you aware that -- I guess it</p> <p>21 was just a couple of months earlier that Health</p> <p>22 Canada issued and published a critical review and</p> <p>23 assessment of the science, which actually included</p> <p>24 a comprehensive review of the epidemiological</p> <p>25 literature? Did you know that?</p>
<p style="text-align: right;">Page 263</p> <p>1 generally. It could mean a million things to</p> <p>2 different people.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q What's it mean to you?</p> <p>5 A It depends upon the context. That's why</p> <p>6 I'm asking from like an epidemiologic standpoint</p> <p>7 as opposed to some other context.</p> <p>8 Q Well, let's take mesothelioma. What are</p> <p>9 the risk factors for mesothelioma?</p> <p>10 A Well, if we're talking about, you know,</p> <p>11 asbestos, for example, as one risk factor, then</p> <p>12 you could use it that way, that -- that an</p> <p>13 exposure elevates the risk of developing a</p> <p>14 disease.</p> <p>15 Q Okay. Let's take talcum powder. Is</p> <p>16 talcum powder a risk factor for ovarian cancer?</p> <p>17 A I don't believe so.</p> <p>18 Q Are there risk factors that are</p> <p>19 modifiable?</p> <p>20 MS. BROWN: Objection to the form.</p> <p>21 THE WITNESS: For what?</p> <p>22 BY MS. PARFITT:</p> <p>23 Q For a disease.</p> <p>24 MS. BROWN: Same objection.</p> <p>25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 265</p> <p>1 MR. LOCKE: Objection.</p> <p>2 MS. BROWN: Objection. That misstates</p> <p>3 the draft assessment.</p> <p>4 THE WITNESS: I'm familiar with it.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Okay. Have you read it?</p> <p>7 A I have.</p> <p>8 Q Have you read it in its entirety?</p> <p>9 A I don't remember if there's like</p> <p>10 appendices or something, but I read all the -- you</p> <p>11 know, the mean part of the text.</p> <p>12 Q Okay. There is also meta-analysis that</p> <p>13 was performed about that same time.</p> <p>14 A Yes. Yeah.</p> <p>15 Q Have you read that?</p> <p>16 A I have.</p> <p>17 Q Okay. Did Health Canada do what we</p> <p>18 would refer to in your world of epidemiology a</p> <p>19 causality assessment?</p> <p>20 MS. BROWN: Objection to the form of the</p> <p>21 question.</p> <p>22 THE WITNESS: I don't know if that's</p> <p>23 what they did.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q What did they do?</p>

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<p style="text-align: right;">Page 266</p> <p>1 MS. BROWN: Objection.</p> <p>2 THE WITNESS: It looks to me as if they</p> <p>3 create -- well, so I don't know. So they -- they</p> <p>4 have their own process. I don't know anything</p> <p>5 about Health Canada, so I don't know what they</p> <p>6 typically do. You know, I've never -- it's unlike</p> <p>7 some other entities where I would kind of</p> <p>8 understand their process because I've read their</p> <p>9 things before.</p> <p>10 I don't -- I don't know anybody</p> <p>11 personally that looks to Health Canada for</p> <p>12 information, so I've never had a conversation with</p> <p>13 anybody about, you know, what their methods are,</p> <p>14 how they go about their business.</p> <p>15 But it looks as if what they were trying</p> <p>16 to do was to try to line up whether there was</p> <p>17 information about where talcum powder is found in</p> <p>18 Canada, so meaning like, you know, how many</p> <p>19 different kinds of products. It looked like they</p> <p>20 were trying to assess some things about dermal</p> <p>21 absorption or not, whether it's ingested or not,</p> <p>22 whether it's inhaled, whether perineal application</p> <p>23 matters or not.</p> <p>24 It seems that they commissioned yet</p> <p>25 another meta-analysis of some sort by Dr. Taher,</p>	<p style="text-align: right;">Page 268</p> <p>1 fair?</p> <p>2 MS. BROWN: Objection to the form.</p> <p>3 THE WITNESS: That looks to be part of</p> <p>4 what they've included in here.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q And you yourself, for purposes of your</p> <p>7 report, looked at case-control studies, cohort</p> <p>8 studies, and meta-analyses, correct?</p> <p>9 A I did.</p> <p>10 Q Okay. Did Health Canada perform a</p> <p>11 Bradford Hill assessment of the evidence?</p> <p>12 MS. BROWN: Objection to the form.</p> <p>13 THE WITNESS: They have a section here.</p> <p>14 I mean, there's something here that -- that</p> <p>15 resembles a Bradford Hill analysis.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Okay. Let me direct your --</p> <p>18 MS. BROWN: Take as long as you need,</p> <p>19 Doctor, to finish your answer.</p> <p>20 THE WITNESS: Well, I just -- like I</p> <p>21 don't know -- I don't know how much leeway there</p> <p>22 is in the world for people to say that they did a</p> <p>23 Bradford Hill analysis just by listing out certain</p> <p>24 keywords, right? I mean it's sort of like a word</p> <p>25 salad exercise to me for some of these cases, and</p>
<p style="text-align: right;">Page 267</p> <p>1 and -- and then created the document that I guess</p> <p>2 that they put out there for -- for public comment</p> <p>3 of some sort.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay. All right. Let's have marked the</p> <p>6 Health Canada report, the draft assessment. And</p> <p>7 we'll have that marked as Exhibit No. 14.</p> <p>8 (Diette Exhibit No. 14 was marked</p> <p>9 for identification.)</p> <p>10 (Counsel conferring.)</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Do you have that in front of you?</p> <p>13 A I do.</p> <p>14 Q Okay. All right. Did the -- did Health</p> <p>15 Canada look at all three types of study designs?</p> <p>16 And by that, I mean case control, cohort, and</p> <p>17 meta-analyses.</p> <p>18 MS. BROWN: Objection to what you mean</p> <p>19 by "look at." Objection to the form.</p> <p>20 THE WITNESS: They've listed -- they've</p> <p>21 listed some of each.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q All right. So they consider for</p> <p>24 purposes of their analysis cohort studies,</p> <p>25 case-control studies and meta-analyses. Is that</p>	<p style="text-align: right;">Page 269</p> <p>1 so --</p> <p>2 BY MS. PARFITT:</p> <p>3 Q I'm sorry. A word what?</p> <p>4 A Word salad.</p> <p>5 Q Word salad.</p> <p>6 A Yeah. Not a technical term, but it's</p> <p>7 kind of a mess, right. So they've got -- like on</p> <p>8 page 19, they've got strength, and strength is a</p> <p>9 Bradford Hill criterion. They don't say whether</p> <p>10 the risk is, you know, weak or strong. They just</p> <p>11 have a list of 30 epidemiologic studies, and they</p> <p>12 say a couple things about some of them being</p> <p>13 statistically significant and -- and so forth.</p> <p>14 Q Okay.</p> <p>15 A And so that -- that isn't really a</p> <p>16 Bradford Hill type analysis about what the --</p> <p>17 whether the strength is high or low.</p> <p>18 And similarly, I would just say like,</p> <p>19 you know, for temporality, you know, what they've</p> <p>20 said here is crazy, right. So it's like --</p> <p>21 Q I'm sorry. What they've said here is</p> <p>22 what?</p> <p>23 A Crazy.</p> <p>24 Q Crazy.</p> <p>25 A Crazy.</p>

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<p>1 Q So let me just ask --</p> <p>2 MS. BROWN: Wait now, he is not done.</p> <p>3 You can follow up when he is done with --</p> <p>4 MS. PARFITT: Fair enough.</p> <p>5 MS. BROWN: Go ahead, Doctor.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Okay. Crazy.</p> <p>8 A Okay. Oh, well, they said like in all</p> <p>9 case-control studies reporting positive outcomes,</p> <p>10 the participants recalled the exposure to talc</p> <p>11 preceded the reported outcome. I mean that is so</p> <p>12 far afield from any realistic epidemiologic</p> <p>13 principle that to say that that somehow informs a</p> <p>14 Bradford Hill analysis -- I don't know, maybe</p> <p>15 "crazy" is the wrong word. Maybe absurd, maybe</p> <p>16 ridiculous. But every person in the world that</p> <p>17 has a particular event or outcome, everything</p> <p>18 about them preceded them. That isn't the same as</p> <p>19 temporality. Temporality in the epidemiologic</p> <p>20 world is demonstrating that time flowed from the</p> <p>21 time of the exposure.</p> <p>22 So, that's why I say like -- you know, I</p> <p>23 read the words here, I see consistency,</p> <p>24 specificity, and so forth, but I don't think their</p> <p>25 application to this is actually a legitimate</p>	<p>1 Did I read that correctly?</p> <p>2 MS. BROWN: You didn't, and actually you</p> <p>3 said "consistently" and the word is "consistent."</p> <p>4 MS. PARFITT: Thank you.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Did I read that correctly with that</p> <p>7 correction?</p> <p>8 A Yes.</p> <p>9 Q Okay. Do you see where the authors</p> <p>10 state that, "Further available data are indicative</p> <p>11 of a causal effect"? Do you see that?</p> <p>12 A I do.</p> <p>13 Q Do you agree with Health Canada that</p> <p>14 there was a causal effect drawn from the genital</p> <p>15 use of talcum powder products and ovarian cancer?</p> <p>16 MS. BROWN: Objection to the form,</p> <p>17 misstates the draft assessment, lacks foundation.</p> <p>18 THE WITNESS: I don't think so, but for</p> <p>19 the reason that -- being that this is -- this is</p> <p>20 at some level -- maybe it's a summary, I don't</p> <p>21 know -- of what they have from above. But their</p> <p>22 input information into what they're concluding</p> <p>23 here is not good. Right.</p> <p>24 I mean look -- look up a couple of</p> <p>25 sentences under "Biologic plausibility," and they</p>
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<p>1 Bradford Hill analysis.</p> <p>2 Q All right. So it's absurd, it's crazy,</p> <p>3 and your opinion is that they did not do a proper</p> <p>4 Bradford Hill analysis. Is that your opinion?</p> <p>5 A It is.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 MS. BROWN: Objection to the form.</p> <p>8 BY MS. PARFITT:</p> <p>9 Q Okay. All right. Let me direct -- did</p> <p>10 they -- let me direct your attention to page 21.</p> <p>11 And we'll put that up on the ELMO.</p> <p>12 All right. Do you see that? Okay?</p> <p>13 A I'm on page 21.</p> <p>14 Q Page 21, and it's the last paragraph,</p> <p>15 and I'll read it.</p> <p>16 "The most recent meta-analysis detailed</p> <p>17 above, Taher, et al., 2018, and consistent with</p> <p>18 the Hill criteria, suggests a small but</p> <p>19 consistently statistically significant positive</p> <p>20 association between ovarian cancer and perineal</p> <p>21 exposure to talc. Further available data are</p> <p>22 indicative of a causal effect. A clear point of</p> <p>23 departure could not be derived from the available</p> <p>24 literature. Consequently, hazard characterization</p> <p>25 is qualitative in nature."</p>	<p>1 say: "The presence of talc in the ovaries has</p> <p>2 been documented," and cite Heller. And they say,</p> <p>3 "The evidence of retrograde transport supports the</p> <p>4 biologic plausibility."</p> <p>5 That Heller study doesn't -- doesn't</p> <p>6 support that, right. So they're -- they're</p> <p>7 stringing things together here that don't</p> <p>8 literally support I think a conclusive statement</p> <p>9 here.</p> <p>10 And also I would just say too, that when</p> <p>11 they say that -- that with the last part of that</p> <p>12 part you read where it says that "The hazard</p> <p>13 characterization is qualitative in nature," well,</p> <p>14 "qualitative" doesn't tell you something about</p> <p>15 whether it's a strong association. I mean they --</p> <p>16 they've resisted using that -- that word here.</p> <p>17 BY MS. PARFITT:</p> <p>18 Q Okay. So my question for you,</p> <p>19 Dr. Diette, is do you disagree with the draft</p> <p>20 Health Canada assessment which found that there</p> <p>21 was a causal relationship between the use of</p> <p>22 genital talcum powder products and ovarian cancer?</p> <p>23 MS. BROWN: Objection. That's not what</p> <p>24 the draft assessment --</p> <p>25 MS. PARFITT: Counsel, objection, form.</p>

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<p>1 MS. BROWN: You're -- it misstates the</p> <p>2 document intentionally attempting to mislead the</p> <p>3 witness.</p> <p>4 MS. PARFITT: Objection.</p> <p>5 THE WITNESS: So I -- first of all,</p> <p>6 so --</p> <p>7 BY MS. PARFITT:</p> <p>8 Q And, Doctor, let me just say something.</p> <p>9 You can explain, but -- I have a question, and</p> <p>10 then you can explain it if you wish.</p> <p>11 And my question is, do you disagree with</p> <p>12 the draft Health Canada assessment which found or</p> <p>13 concluded that there was a causal relationship</p> <p>14 between the use of genital talcum powder product</p> <p>15 and ovarian cancer?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 MS. BROWN: Objection to the form.</p> <p>18 You can answer it truthfully and</p> <p>19 accurately.</p> <p>20 THE WITNESS: I can't answer it.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q You can't -- wait one second.</p> <p>23 A I cannot answer it.</p> <p>24 Q You can't answer the question as to</p> <p>25 whether or not you agree that they concluded that</p>	<p>1 talcum powder products used in the genital area</p> <p>2 and ovarian cancer? That's the question.</p> <p>3 MS. BROWN: Objection to the form of the</p> <p>4 question, misstates the document --</p> <p>5 BY MS. PARFITT:</p> <p>6 Q You may answer.</p> <p>7 A Is there a specific sentence in there</p> <p>8 that says that?</p> <p>9 Q It's the question that I've asked you.</p> <p>10 A Oh, so I can't answer it. I can answer</p> <p>11 the --</p> <p>12 Q Is there a specific question --</p> <p>13 MS. BROWN: Wait, wait, let him finish.</p> <p>14 BY MS. PARFITT:</p> <p>15 Q -- 20, 21, 28, and Roman numeral iii?</p> <p>16 MS. BROWN: What?</p> <p>17 THE WITNESS: If there's a specific</p> <p>18 sentence that says that, and you want me to agree</p> <p>19 or disagree, I can agree or disagree with that</p> <p>20 sentence.</p> <p>21 What I can't agree with is an entire</p> <p>22 document because I think it's not fair. I'm not</p> <p>23 talking about just this one. I think, you know,</p> <p>24 lawyers like to do this, right. They like to say,</p> <p>25 Do you agree with a such-and-such paper. Well,</p>
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<p>1 there was a causal relationship between talcum</p> <p>2 powder products and ovarian cancer?</p> <p>3 A So that --</p> <p>4 MS. BROWN: Objection to the form,</p> <p>5 misstates the document.</p> <p>6 Go ahead, Doctor.</p> <p>7 THE WITNESS: Yeah, your question has</p> <p>8 morphed, right. And so I'm still stuck on the way</p> <p>9 it came out when you first said it.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Then let's go -- we'll go with the one</p> <p>12 the --</p> <p>13 MS. BROWN: Wait, let him finish.</p> <p>14 MS. PARFITT: No. Excuse me.</p> <p>15 MS. BROWN: Counsel, you've been doing</p> <p>16 that all day. You cannot cut this witness off.</p> <p>17 He needs to finish.</p> <p>18 MS. PARFITT: I'm not -- he asked for</p> <p>19 what question I wanted to ask, so let me ask it</p> <p>20 again.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q Do you have -- is it -- do you -- strike</p> <p>23 that.</p> <p>24 Do you agree or disagree with Health</p> <p>25 Canada and their assessment of causality between</p>	<p>1 it's nonsense. You don't agree with the paper.</p> <p>2 You agree with the finding or you agree with the</p> <p>3 conclusion, but not with the entire thing.</p> <p>4 So here what I'm saying is, there's an</p> <p>5 entire document here. There's some good stuff and</p> <p>6 some bad stuff, and I can point out some of --</p> <p>7 some of each.</p> <p>8 But the point here is if there's a</p> <p>9 specific statement that they made that says --</p> <p>10 about causation, I would just like to see that</p> <p>11 particular statement and tell you whether I can</p> <p>12 agree with it or not.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Well, look at page 28 -- or excuse me,</p> <p>15 21, the page we were on.</p> <p>16 Do you have that in front of you?</p> <p>17 A I do.</p> <p>18 Q Okay. "Available data are</p> <p>19 indicative" --</p> <p>20 MS. BROWN: Counsel, where are you?</p> <p>21 MS. PARFITT: It's the paragraph just</p> <p>22 above "Exposure Assessment." It says the recent</p> <p>23 -- we just read it.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q "The most recent meta-analysis detailed</p>

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<p style="text-align: right;">Page 278</p> <p>1 above, Taher, and consistent with the Hill 2 criteria, suggests a small but consistent 3 statistically significant positive association 4 between ovarian cancer and perineal exposure to 5 talc. Further available data are indicative of a 6 causal effect." 7 MS. BROWN: What's the question? 8 BY MS. PARFITT: 9 Q Do you agree with the conclusions of 10 Health Canada? 11 MS. BROWN: Objection to the form. This 12 is not the conclusion section. 13 THE WITNESS: So, first of all, the -- 14 the first sentence that you read there talks about 15 a significant positive association, which isn't 16 the same as cause. Right. And then they say, 17 "Further available data are indicative of..." 18 I -- I think if you're trying to say 19 that something causes something, you come out and 20 you say it. You don't say, "Further data are 21 indicative of it." So I -- I don't think this 22 statement says talcum powder causes ovarian 23 cancer. 24 BY MS. PARFITT: 25 Q Okay. So your quarrel with Health</p>	<p style="text-align: right;">Page 280</p> <p>1 A That sentence is there. 2 Q All right. Okay. 3 MS. BROWN: Counsel, if you're moving to 4 another area, would -- 5 MS. PARFITT: I am. 6 MS. BROWN: Would this be a good time 7 for a break? 8 MS. PARFITT: Yeah. I'm going to move 9 on and change gears. 10 THE VIDEOGRAPHER: The time is 1:52 11 p.m., and we are off the record. 12 (Recess.) 13 THE VIDEOGRAPHER: The time is 14 2:04 p.m., and we're back on the record. 15 BY MS. PARFITT: 16 Q Dr. Diette, you mentioned before the 17 break the Heller article, and so I don't misquote 18 you, what was your position with regard to Heller 19 and what it stood for? 20 A I think if we're talking about the -- 21 the right one, it's the one where the ovaries were 22 removed from, I think, 24 women, and that 12 -- 12 23 had said that they were talcum powder users and 12 24 not, but they found a -- they found a similar 25 amount of talc in ovaries regardless of whether</p>
<p style="text-align: right;">Page 279</p> <p>1 Canada is the fact that they didn't say it, Talcum 2 powder products used in the genital area cause 3 ovarian cancer. 4 A Well -- 5 Q You quarrel with their language. Is 6 that what you're saying? 7 A Well, I quarrel -- 8 MS. BROWN: Objection. Misstates his 9 testimony. 10 THE WITNESS: I quarrel a little with 11 you, I think -- I'm sorry. 12 THE REPORTER: I'm sorry, your -- 13 MS. BROWN: I just want to object to the 14 question as misstating your testimony. 15 THE WITNESS: Because I think your 16 initial question before you read it literally was 17 about whether or not they said that it causes it, 18 and I don't think that it said that. 19 And -- and I think otherwise that there 20 are some flaws in the -- in the information that 21 they've used up above to reach this -- I guess 22 it's a conclusion. I don't know if it is or not. 23 BY MS. PARFITT: 24 Q Okay. Does it say, "Further available 25 data are indicative of a causal effect"?</p>	<p style="text-align: right;">Page 281</p> <p>1 they were users or not. 2 Q Okay. Is -- is it your opinion that 3 talc cannot migrate to the ovaries? 4 A I don't know that it can. I -- if it's 5 found there, I'm not sure how it got there. 6 Q Is it your opinion that asbestos can 7 migrate to the ovaries? 8 MS. BROWN: Objection to the form. 9 THE WITNESS: I've seen -- I don't think 10 I've seen anything that shows for sure that it 11 can. 12 BY MS. PARFITT: 13 Q Okay. If asbestos was found in the 14 ovaries, how would it get there? 15 MS. BROWN: Objection to the form. 16 THE WITNESS: So I don't know. I mean, 17 it's -- I don't know of a worked-out mechanism 18 that shows how it got there. 19 (Diette Exhibit No. 15 was marked 20 for identification.) 21 BY MS. PARFITT: 22 Q Let me show you what's been marked as 23 Heller Exhibit No. 15. And it is a 1996 article 24 entitled "Asbestos Exposure and Ovarian Fiber 25 Burden."</p>

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<p style="text-align: right;">Page 282</p> <p>1 (Counsel conferring.)</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Do you have that in front of you?</p> <p>4 A I do.</p> <p>5 Q All right. Now, this was a different</p> <p>6 Heller article than the one you were referring to?</p> <p>7 A Thank you, yes.</p> <p>8 Q Okay. All right. Now, let me direct</p> <p>9 your attention to the Abstract section, the last</p> <p>10 paragraph.</p> <p>11 Okay. And it states: "This study</p> <p>12 demonstrates that asbestos can reach the ovary.</p> <p>13 Although the number of subjects is small, asbestos</p> <p>14 appears to be present in ovarian tissue more</p> <p>15 frequently and in higher amounts in women with a</p> <p>16 documentable exposure history."</p> <p>17 Did I read that correctly?</p> <p>18 A Yes.</p> <p>19 Q All right. Do you agree with that</p> <p>20 statement?</p> <p>21 MS. BROWN: Objection to the form.</p> <p>22 THE WITNESS: Give me one sec, because</p> <p>23 I -- it's been a while since I looked at this.</p> <p>24 MS. BROWN: Take your time, Doctor.</p> <p>25 THE WITNESS: (Peruses document.) Yeah,</p>	<p style="text-align: right;">Page 284</p> <p>1 A And it's about the middle of the</p> <p>2 paragraph, and it says it is -- it says -- right</p> <p>3 above it, it says: "None of the exposed subjects</p> <p>4 in the study was directly occupationally exposed</p> <p>5 but all were passively exposed to household</p> <p>6 contact. It is unclear why so many of the women</p> <p>7 giving no exposure history did have detectable</p> <p>8 asbestos in their ovaries, although it is known</p> <p>9 that there is a background level of asbestos in</p> <p>10 the lung tissue of non-exposed individuals."</p> <p>11 So I -- I don't know. I just don't --</p> <p>12 that this -- this cements the idea that -- that we</p> <p>13 know something about how asbestos, you know, can</p> <p>14 get to the ovaries.</p> <p>15 Q All right. Let me direct your attention</p> <p>16 to the bottom of 438, top of 439.</p> <p>17 At the bottom of 438, it says "There</p> <p>18 is," and then it goes on to the top of 439:</p> <p>19 "There is evidence of transport of particulate</p> <p>20 matter into the female perineum by the</p> <p>21 transvaginal route."</p> <p>22 A I apologize, I -- I'm not with you, and</p> <p>23 I just --</p> <p>24 Q Oh, sure.</p> <p>25 A I'm just trying to --</p>
<p style="text-align: right;">Page 283</p> <p>1 again, like -- so not entirely.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q What part -- what part --</p> <p>4 MS. BROWN: Let him finish.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q What part do you agree with?</p> <p>7 A Well, the -- I think that it's -- it's</p> <p>8 not -- well, so the study demonstrates that</p> <p>9 asbestos can reach the ovary. I guess if it's</p> <p>10 definitely there, then -- and it got there somehow</p> <p>11 and it wasn't through contamination, you know, of</p> <p>12 the procedure that -- that led to it, you could --</p> <p>13 you know, you could infer that there's some way</p> <p>14 that it got there.</p> <p>15 I think it doesn't tell us anything</p> <p>16 about how to make sense of that. And what I was</p> <p>17 looking for that I remember is that they said that</p> <p>18 it's unclear why so many women giving no exposure</p> <p>19 history did have detectable asbestos in their</p> <p>20 ovaries.</p> <p>21 Q Where do you see that?</p> <p>22 A I'm sorry. I'm on 439.</p> <p>23 Q Thank you.</p> <p>24 A And in the Conclusion paragraph.</p> <p>25 Q Mm-hmm. Yes.</p>	<p style="text-align: right;">Page 285</p> <p>1 Q It's right here, upper corner, 439.</p> <p>2 A Got you.</p> <p>3 Q Okay?</p> <p>4 A Yep.</p> <p>5 Q All right, again. "There is evidence of</p> <p>6 transport of particulate matter into the female</p> <p>7 perineum by the transvaginal route in both human</p> <p>8 and animal studies." It cites Egli and Newton,</p> <p>9 1961. It cites Henderson, 1986; Venter -- and I'm</p> <p>10 sure I'll destroy this name -- Iturralde, 1979;</p> <p>11 Whittemore, 1988. "Suggested that vaginal</p> <p>12 exposure to particulate matter such as asbestos</p> <p>13 and talc was a potential risk factor for</p> <p>14 intraperitoneal ovarian exposure. Her conclusion</p> <p>15 was based on finding that in talc exposed women, a</p> <p>16 previous history of hysterectomy or tubal</p> <p>17 ligation, which blocks perineum access, was</p> <p>18 protective against ovarian cancer."</p> <p>19 It goes on to say: "Talc has been</p> <p>20 implicated as a possible etiological agent in</p> <p>21 ovarian cancer," citing Harlow '89 and '92, "and</p> <p>22 is related to the asbestos problem in several</p> <p>23 ways. Aside from the chemical similarities</p> <p>24 between the two, many cosmetic talcs contained</p> <p>25 significant amounts of asbestos, particularly</p>

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<p style="text-align: right;">Page 286</p> <p>1 prior to '70 -- 1976, Cramer, 1982. The</p> <p>2 significance of this detection of talc in the</p> <p>3 majority of exposed women and in all women giving</p> <p>4 no exposure history is unclear and further studies</p> <p>5 are underway to further elucidate this question."</p> <p>6 Did I read that correctly?</p> <p>7 A Yes.</p> <p>8 Q Question: Are there chemical</p> <p>9 similarities between cosmetic talcs and asbestos?</p> <p>10 MS. BROWN: Objection to the form.</p> <p>11 THE WITNESS: So some of the same --</p> <p>12 some of the same features chemically are present</p> <p>13 in both.</p> <p>14 BY MS. PARFITT:</p> <p>15 Q All right. Set that aside for a minute.</p> <p>16 We may come back to that.</p> <p>17 Dr. Diette, for purposes of your</p> <p>18 opinions in this case, you have stated that the</p> <p>19 cohort studies lack statistical significance, and</p> <p>20 only a subset of the case-control studies are</p> <p>21 statistically significant. Therefore, there is a</p> <p>22 disparity and inconsistency between cohorts and</p> <p>23 case control.</p> <p>24 Have I summed it up pretty well?</p> <p>25 A That -- that's one of the -- one of the</p>	<p style="text-align: right;">Page 288</p> <p>1 If you know.</p> <p>2 THE WITNESS: Can I assume or --</p> <p>3 MS. BROWN: No, if you don't know, don't</p> <p>4 answer. Then you have no basis to answer the</p> <p>5 question.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q My question is, do you know what Ken</p> <p>8 Rothman's area of expertise is?</p> <p>9 MS. BROWN: Objection.</p> <p>10 THE WITNESS: Well, he's -- he's made a</p> <p>11 career out of -- out of case-control studies and</p> <p>12 articulating, you know, features of the design and</p> <p>13 so forth.</p> <p>14 BY MS. PARFITT:</p> <p>15 Q All right. Is he an epidemiologist?</p> <p>16 A Well, that's what I was trying to</p> <p>17 remember. Like, I would only be guessing. Like,</p> <p>18 I assume for him to be in that role, he would be,</p> <p>19 but there are people that come to epidemiology</p> <p>20 from other -- you know, other backgrounds, and so</p> <p>21 I just don't know his credentials.</p> <p>22 Q Okay. What about Sander Greenland, do</p> <p>23 you know who he is?</p> <p>24 A I know the name, but I don't know him.</p> <p>25 Q Okay. Have you ever -- do you know what</p>
<p style="text-align: right;">Page 287</p> <p>1 bits of evidence of inconsistency.</p> <p>2 Q Okay. Would you agree that to disregard</p> <p>3 study results based upon whether they are</p> <p>4 statistically significant or not statistically</p> <p>5 significant would be a mistake?</p> <p>6 MS. BROWN: Objection to the form.</p> <p>7 Counsel, is there something you're reading from</p> <p>8 that --</p> <p>9 MS. PARFITT: No. Actually, my notes,</p> <p>10 and he doesn't get those. Thank you.</p> <p>11 THE WITNESS: Okay. So "disregard" is</p> <p>12 pretty severe. Right. So I don't think that</p> <p>13 somebody should disregard any study, unless it's,</p> <p>14 you know, fraudulent or, you know, created out of</p> <p>15 nowhere. So I think that people should regard the</p> <p>16 findings and interpret them appropriately.</p> <p>17 So I think that would be an overly</p> <p>18 strong thing to do, which would be to disregard it</p> <p>19 simply because it's statistically insignificant.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Okay. Do you know who Ken Rothman is?</p> <p>22 A I -- I know of him. I don't know him</p> <p>23 personally.</p> <p>24 Q Okay. What does he do for a living?</p> <p>25 MS. BROWN: Objection to the form.</p>	<p style="text-align: right;">Page 289</p> <p>1 kind of scientist Sander Greenland is?</p> <p>2 MS. BROWN: Objection. Form.</p> <p>3 THE WITNESS: I do not.</p> <p>4 MS. BROWN: Foundation.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Okay. All right. Do you know Timothy</p> <p>7 Lash?</p> <p>8 MS. BROWN: Objection. Foundation.</p> <p>9 THE WITNESS: I don't know the name.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Okay. Do you know what kind of</p> <p>12 scientist Tim -- Timothy Lash is?</p> <p>13 MS. BROWN: Same objection.</p> <p>14 THE WITNESS: It would be hard to know</p> <p>15 that --</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Okay.</p> <p>18 A -- without knowing him.</p> <p>19 Q Okay. Let me show you what we will have</p> <p>20 marked as Exhibit No. -- 61? 16.</p> <p>21 MR. TISI: We're not that high.</p> <p>22 (Diette Exhibit No. 16 was marked</p> <p>23 for identification.)</p> <p>24 BY MS. PARFITT:</p> <p>25 Q And I will -- and I will represent,</p>

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<p>1 Dr. Diette, that this is Chapter 2 out of the 2 Third Edition, Modern Epidemiology. 3 Do you see that? 4 A I do. 5 Q Okay. And if you look at the front of 6 it, it has three authors. 7 Do you see that? 8 A I do. 9 Q Okay. The first one is Ken Rothman. Do 10 you see that? 11 A Correct. 12 Q The second one is Sander Greenland. 13 A Correct. 14 Q And the third author is Tim Lash. Do 15 you see that? 16 A I do. 17 Q And they are -- the book that they have 18 authored is called Modern Epidemiology, Third 19 Edition. Do you see that? 20 A I do. 21 Q Okay. Let me -- let me direct your 22 attention to page 27. 23 MS. BROWN: Counsel, are you going to 24 lay a foundation for the use of this document? 25 MS. PARFITT: I can just ask a question.</p>	<p>1 MS. BROWN: I have a continuing 2 foundation. 3 MS. PARFITT: That's fine, Counsel. 4 MS. BROWN: -- objection to this 5 exhibit, for which no foundation has been laid. 6 BY MS. PARFITT: 7 Q All right. Again, I'm referring to the 8 category consistency which I represent that is in 9 Chapter 2 of the Rothman book, and we can just go 10 ahead and circle the paragraph that starts: "One 11 mistake in implementing the consistency criterion 12 is so common that it deserves special mention. It 13 is sometimes claimed that a literature or set of 14 results is inconsistent simply because some 15 results are statistically significant, and some 16 are not." 17 Did I read that correctly? 18 A You did. 19 Q "This sort of evaluation is completely 20 fallacious, even if one accepts the use of 21 significant testing methods." 22 Did I read that correctly? 23 A You did. 24 Q All right. Do you agree with that 25 statement?</p>
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<p>1 I can do that. 2 BY MS. PARFITT: 3 Q Let me ask a question. 4 "To claim that literature, scientific 5 literature, or a set of results reported in 6 scientific literature is inconsistent simply 7 because some results are statistically 8 significant, and some are not, would be completely 9 fallacious, even if one accepts the use of 10 significant testing methods." 11 Do you agree with that statement? 12 MR. LOCKE: Objection. 13 MS. BROWN: Objection. Form, 14 foundation. 15 THE WITNESS: Is that a hybrid of a 16 couple of things? Because I thought I was reading 17 with you, and then I might have left off. 18 BY MS. PARFITT: 19 Q Well, why don't we do this. We'll put 20 it back on the ELMO, and I'll represent that it is 21 a -- 22 A Yeah, I don't doubt you. I just -- 23 Q Sure, no worries. That's fine. 24 A It goes on to a different sentence. 25 Q That's fine.</p>	<p>1 MR. LOCKE: Objection. 2 THE WITNESS: So wait a minute, I just 3 want to -- so there's a couple of statements 4 there. I think the part that makes it agreeable 5 is to say that -- that if it's claimed that 6 results are -- and I'm paraphrasing -- 7 BY MS. PARFITT: 8 Q Sure. 9 A -- but that the results are inconsistent 10 simply, and the word "simply" to me is really 11 important here because it suggests that somebody 12 would be not looking at the entire universe of 13 evidence that they have available. 14 So I think if you just took a quick look 15 at studies and said some were significant and some 16 weren't and left it at that, you know, it's a 17 pretty strong statement, but I think -- I think 18 that would be a mistake to only do that. 19 Q All right. Now, you're not a 20 statistician, correct? 21 A I'm not a statistician. 22 Q Okay. And you're not a biostatistician. 23 A I'm not a biostatistician. 24 Q Okay. Do you know who Daniel Ford is? 25 A I do.</p>

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<p>1 Q Okay. Who is Daniel Ford?</p> <p>2 A If it's the one that --</p> <p>3 Q Daniel E. Ford.</p> <p>4 A I don't know his middle name, but</p> <p>5 there's a Dan Ford at our -- at our place.</p> <p>6 Q Okay. Is the Dan Ford you know vice</p> <p>7 dean for clinical investigation, Johns Hopkins</p> <p>8 School of Medicine?</p> <p>9 A Yes.</p> <p>10 Q Okay. Is he a friend of yours?</p> <p>11 A We're friendly. I mean, we don't hang</p> <p>12 out, though.</p> <p>13 Q Now, he is with the Institute for</p> <p>14 Clinical and Translational Research; is that</p> <p>15 correct?</p> <p>16 A He has been. I'm just trying to think</p> <p>17 if that still exists. Because I know there was a</p> <p>18 funding issue, so -- but he -- he certainly was in</p> <p>19 that role, and he may still be.</p> <p>20 Q He may what?</p> <p>21 A He may still be. I just -- I just -- I</p> <p>22 thought I had heard that the ICTRs were going to</p> <p>23 be not funded anymore.</p> <p>24 Q Okay.</p> <p>25 A Maybe it's true, maybe not; but I'm just</p>	<p>1 Q Do you know about that?</p> <p>2 A I'm aware of that.</p> <p>3 Q Okay. Now, are you -- did you read</p> <p>4 Dr. Bowman's deposition?</p> <p>5 A I did.</p> <p>6 Q Okay. Did you see that in Dr. Bowman's</p> <p>7 deposition?</p> <p>8 A I saw -- I'm just trying to remember. I</p> <p>9 saw the Nature article, I think that is more</p> <p>10 recently published than -- you said 2016?</p> <p>11 Q Originally, yes.</p> <p>12 A Yeah, but I can't remember if 2016 was</p> <p>13 in her deposition, but for sure the more recent</p> <p>14 one.</p> <p>15 Q The one in 2019?</p> <p>16 A Exactly right, yeah.</p> <p>17 Q All right. All right. Let me show you</p> <p>18 then what's been marked as -- or will be marked as</p> <p>19 17. And it is the March 2019 --</p> <p>20 (Counsel conferring.)</p> <p>21 BY MS. PARFITT:</p> <p>22 Q Okay. Let me show you what we will have</p> <p>23 marked as 17, a study that appeared in The</p> <p>24 American Statistician in 2019. It's Volume 73,</p> <p>25 and it's called "Moving to a World Beyond P <</p>
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<p>1 saying for sure he was part of that.</p> <p>2 Q Mm-hmm. Okay. Sure. Okay.</p> <p>3 All right. Are you a member -- and I'm</p> <p>4 assuming you're not because you're not a</p> <p>5 statistician, but I should assume nothing.</p> <p>6 Are you a member of the American</p> <p>7 Statistical Association?</p> <p>8 A I am not.</p> <p>9 Q Okay. Do you know who they are?</p> <p>10 A Not -- not really. I mean, it -- it</p> <p>11 sounds like the name gives them away, but I</p> <p>12 don't -- I don't know, you know, who they are as</p> <p>13 an entity otherwise.</p> <p>14 Q That's fair. Okay.</p> <p>15 Are you aware that due to a widespread</p> <p>16 misuse by scientists and researchers regarding</p> <p>17 statistical significance and p-values, that the</p> <p>18 American Statistical Association issued a</p> <p>19 statement back in 2016 warning the scientific</p> <p>20 community of this misuse and urging them to cease</p> <p>21 and desist with the p-value?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 MS. BROWN: Objection to the form, lacks</p> <p>24 foundation, misrepresents the facts.</p> <p>25 BY MS. PARFITT:</p>	<p>1 0.05."</p> <p>2 Do you see that?</p> <p>3 A Actually, I was just sort of flipping</p> <p>4 through to see what I'm looking at. Oh, so the</p> <p>5 title, yes.</p> <p>6 Q Okay. Is this a document you were</p> <p>7 referring to?</p> <p>8 A No.</p> <p>9 Q No?</p> <p>10 A I was referring to the one in Nature</p> <p>11 that I think reports about this.</p> <p>12 Q Yes. Okay. Let's go ahead and get that</p> <p>13 marked, and we'll talk about all three.</p> <p>14 (Diette Exhibit No. 17 was marked</p> <p>15 for identification.)</p> <p>16 MS. PARFITT: Let's have marked as</p> <p>17 Exhibit No. 18.</p> <p>18 (Diette Exhibit No. 18 was marked</p> <p>19 for identification.)</p> <p>20 BY MS. PARFITT:</p> <p>21 Q And I will represent that 18 is a Sander</p> <p>22 Greenland article that appeared in Nature on</p> <p>23 March 2019.</p> <p>24 Okay. Is that the article you were</p> <p>25 referring to?</p>

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<p>1 A Yes.</p> <p>2 Q Okay. Have you had an opportunity to</p> <p>3 read Exhibit No. 18?</p> <p>4 A I have.</p> <p>5 Q Okay. Exhibit 17, which is the</p> <p>6 Wasserstein article, have you had an opportunity</p> <p>7 to read it prior to today?</p> <p>8 A This -- this one, no.</p> <p>9 Q Okay. All right. Let's first take a</p> <p>10 moment and discuss what's been marked as 18.</p> <p>11 Excuse me. No, 18. 18.</p> <p>12 Are you aware that due to the American</p> <p>13 Statistical Society's concern of the misuse of</p> <p>14 statistical significance and p-value, that they</p> <p>15 literally used their March 2019 research paper and</p> <p>16 devoted attention to this issue and attached</p> <p>17 almost 40 papers on statistical inference? Are</p> <p>18 you aware of that?</p> <p>19 MR. LOCKE: Objection.</p> <p>20 MS. BROWN: Objection to the form,</p> <p>21 misstates the facts. Are you referring to</p> <p>22 Exhibit 17?</p> <p>23 MS. PARFITT: No. 17. 17.</p> <p>24 MS. BROWN: Yes, 17.</p> <p>25 MS. PARFITT: No, I'm not referring to</p>	<p>1 MS. BROWN: -- before you ask him any</p> <p>2 questions about it.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q I just have a couple of questions about</p> <p>5 it.</p> <p>6 MS. BROWN: Take as long as you need.</p> <p>7 THE WITNESS: (Peruses document.)</p> <p>8 BY MS. PARFITT:</p> <p>9 Q And I just have a couple of questions</p> <p>10 about it.</p> <p>11 A Sure.</p> <p>12 MS. BROWN: He's never seen it, so he</p> <p>13 needs --</p> <p>14 MS. PARFITT: That's fine.</p> <p>15 MS. BROWN: -- as long as he needs.</p> <p>16 MS. PARFITT: He can take -- yeah.</p> <p>17 THE WITNESS: Well, I won't be able to</p> <p>18 read it in --</p> <p>19 BY MS. PARFITT:</p> <p>20 Q Okay. Let me just --</p> <p>21 A -- in realtime today.</p> <p>22 Q -- ask you a couple of questions. I'm</p> <p>23 not expecting you to digest it.</p> <p>24 All right. The first paragraph, it</p> <p>25 says -- do you have it up there?</p>
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<p>1 that at all. I'm just -- I'm asking a question.</p> <p>2 MS. BROWN: Objection. Lacks</p> <p>3 foundation, misstates the facts.</p> <p>4 THE WITNESS: I saw that there was a --</p> <p>5 a journal issue that had many articles. I</p> <p>6 didn't -- I don't know what the count was, but</p> <p>7 there -- it's probably the same thing we're</p> <p>8 talking about, but I'm not sure.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q Okay. Did you have a chance to read</p> <p>11 those 40 or so articles?</p> <p>12 MS. BROWN: Objection to the form.</p> <p>13 THE WITNESS: I -- I wish I had that</p> <p>14 kind of time, but --</p> <p>15 BY MS. PARFITT:</p> <p>16 Q You and me both.</p> <p>17 A Yeah.</p> <p>18 Q Okay. All right. Let's stay a few</p> <p>19 minutes on 17, and we'll put it up on the ELMO.</p> <p>20 And it starts --</p> <p>21 MS. BROWN: Counsel, he's never seen 17</p> <p>22 before, so he's going to need a minute to</p> <p>23 familiarize himself with it --</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Take a minute to familiarize yourself.</p>	<p>1 "Some of you exploring this special</p> <p>2 issue of The American Statistician might be</p> <p>3 wondering if it's a scolding from the pedantic</p> <p>4 statisticians lecturing you about what not to do</p> <p>5 with p-values, without offering any real ideas of</p> <p>6 what to do about the very hard problem separating</p> <p>7 signal from noise in data and making decisions</p> <p>8 under uncertainty. Fear not, in this issue,</p> <p>9 thanks to 43 innovative and thought-provoking</p> <p>10 papers from forward-looking statisticians, help is</p> <p>11 on the way."</p> <p>12 Do you see that?</p> <p>13 A I do.</p> <p>14 Q Okay. Did I read that correctly?</p> <p>15 A You did.</p> <p>16 Q And is that the 43 papers that you were</p> <p>17 speaking of that you didn't have time to read?</p> <p>18 MS. BROWN: Objection to the form, lacks</p> <p>19 foundation.</p> <p>20 THE WITNESS: I -- I think so. I mean,</p> <p>21 this sounds familiar. I think it's what I was</p> <p>22 looking at, but I'm not -- not a hundred percent</p> <p>23 sure.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Okay. If you'd look at right under</p>

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<p style="text-align: right;">Page 302</p> <p>1 "Don't' is Not Enough." Do you see that?</p> <p>2 A Yes.</p> <p>3 Q All right. The first sentence says:</p> <p>4 "There's not much we can say here about the perils</p> <p>5 of p-values and significance testing that hasn't</p> <p>6 already -- that hasn't been said already for</p> <p>7 decades."</p> <p>8 Did I read that correctly?</p> <p>9 A Yes.</p> <p>10 Q And then it goes down to the first one:</p> <p>11 "Don't base your conclusions solely on whether an</p> <p>12 association or effect was found to be</p> <p>13 statistically significant. The p-value passed</p> <p>14 some arbitrary threshold such as $p < 0.05$."</p> <p>15 Did I read that correctly?</p> <p>16 A Yes.</p> <p>17 Q Do you agree with that statement?</p> <p>18 MR. LOCKE: Objection.</p> <p>19 THE WITNESS: So there's a lot to this,</p> <p>20 right. I mean because, I mean, the lead in to it,</p> <p>21 it says -- it says that there's not much to say</p> <p>22 here, you know --</p> <p>23 BY MS. PARFITT:</p> <p>24 Q That hasn't been said.</p> <p>25 A -- hasn't been said for decades.</p>	<p style="text-align: right;">Page 304</p> <p>1 statistical significance or lack thereof."</p> <p>2 Do you agree with that statement?</p> <p>3 MS. BROWN: Objection to the form.</p> <p>4 And, Doctor, if you need to read the</p> <p>5 whole article to answer these questions --</p> <p>6 MS. PARFITT: Counsel, don't coach the</p> <p>7 witness.</p> <p>8 MS. BROWN: -- you should do that.</p> <p>9 Yeah, but you are knowingly --</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Go ahead, Doctor.</p> <p>12 MS. BROWN: -- putting a document in</p> <p>13 front of him that he's never seen, so we're not</p> <p>14 going to sit here --</p> <p>15 BY MS. PARFITT:</p> <p>16 Q I'm asking you a question, Dr. Diette --</p> <p>17 MS. BROWN: -- and play cherry-</p> <p>18 picking statements to get --</p> <p>19 BY MS. PARFITT:</p> <p>20 Q -- do you agree that one should not</p> <p>21 conclude anything about scientific or practical</p> <p>22 importance based on statistical significance or</p> <p>23 lack thereof? Do you agree with that?</p> <p>24 MR. LOCKE: Objection.</p> <p>25 MS. BROWN: Same objection.</p>
<p style="text-align: right;">Page 303</p> <p>1 MS. BROWN: Wait, wait, let him finish.</p> <p>2 THE WITNESS: And -- and that's --</p> <p>3 that's pretty -- well, I can't say it's true</p> <p>4 because I haven't read this, so I don't know</p> <p>5 what's in here, but the debate about p-values and</p> <p>6 statistical significance isn't brand new. I mean,</p> <p>7 I've been talking about it with colleagues for</p> <p>8 decades, and I'm sure there were people decades</p> <p>9 before me. So that -- that part rings true.</p> <p>10 And I think -- you know, I don't know</p> <p>11 when they're talking about conclusions. That's</p> <p>12 a -- that's a pretty broad topic, but I think the</p> <p>13 word "solely" is very helpful there, that we</p> <p>14 shouldn't be making decisions solely on whether</p> <p>15 something is statistically significant. And</p> <p>16 there's more to it than that.</p> <p>17 BY MS. PARFITT:</p> <p>18 Q Okay.</p> <p>19 A But that's a -- that's a super broad</p> <p>20 statement, and I don't know, you know, in every</p> <p>21 circumstance whether that would be agreeable or</p> <p>22 not.</p> <p>23 Q Okay. Look at the last bullet there.</p> <p>24 It states: "Don't conclude anything about</p> <p>25 scientific or practical importance based on</p>	<p style="text-align: right;">Page 305</p> <p>1 THE WITNESS: So, anyway, I think by</p> <p>2 saying "don't conclude anything," I think makes</p> <p>3 this not a very agreeable statement for me.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay. All right. Let's turn to what</p> <p>6 you did read, and that's Exhibit 18.</p> <p>7 Do you have that, Doctor?</p> <p>8 A I do.</p> <p>9 Q Okay. And this is an article that</p> <p>10 appeared in Nature back in March of 2019, correct?</p> <p>11 A That's right.</p> <p>12 Q Okay. And you did have a chance to read</p> <p>13 this; is that correct?</p> <p>14 A I did.</p> <p>15 Q Okay. And under the section "Pervasive</p> <p>16 Problem," do you see that?</p> <p>17 A Yes.</p> <p>18 Q Okay. It states: "Let's be clear about</p> <p>19 what must stop. We should never conclude there is</p> <p>20 no difference or no association just because the</p> <p>21 p-value is larger than the threshold, such as</p> <p>22 0.05, or equivalently because a confidence</p> <p>23 interval includes zero. Neither should we</p> <p>24 conclude that two studies conflict because one had</p> <p>25 a statistically significant result and the other</p>

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<p style="text-align: right;">Page 306</p> <p>1 did not. These errors waste research efforts and 2 misinform policy decisions." 3 Did I read that correctly? 4 A You did. 5 Q Do you agree with that? 6 MS. BROWN: Objection to the form. 7 MR. LOCKE: Objection. 8 THE WITNESS: To me it's overly broad, 9 and I think that -- I think that if we go through 10 and we find a sentence or two in here that are 11 agreeable or not, there's a -- there's a much, 12 much bigger proposition here about what's going 13 on, and I don't think it boils down to any one of 14 these sentences. 15 And I think this looks like a passionate 16 opinion piece, right. That's calling it an 17 article, but it's a commentary. And, you know, 18 these guys might believe that, but I don't -- I 19 don't think it's a mainstream view, and it's not 20 my view, you know, without any qualifications 21 that -- that that statement is correct either. 22 Q Okay. Are you aware that over 800 23 statisticians and scientists signed on to this 24 document to push the concept of abandoning 25 statistical significance?</p>	<p style="text-align: right;">Page 308</p> <p>1 is that correct? 2 A I didn't. 3 MS. BROWN: Asked and answered. 4 BY MS. PARFITT: 5 Q All right. Now, let me have marked now 6 as Exhibit No. 19. 7 (Diette Exhibit No. 19 was marked 8 for identification.) 9 BY MS. PARFITT: 10 Q Do you have that, Doctor? 11 Take a look at that, if you will. 12 A (Peruses document.) So is this meant to 13 be a couple of things? 14 Q It's two things. I will represent to 15 you that the face sheet states "Johns Hopkins 16 Institute for Clinical and Translational 17 Research." The American Statistician special 18 issue, "Moving to a World Beyond P < 0.05." It's 19 dated March 25, 2019. It has The American 20 Statistician on the side. 21 A What are we -- I'm confused, though. 22 This is -- this is Exhibit 17 with something 23 attached to it or -- 24 Q You know, that's exactly it. And if you 25 look at Exhibit 19 --</p>
<p style="text-align: right;">Page 307</p> <p>1 MS. BROWN: Objection to the form. 2 MR. LOCKE: Objection. 3 THE WITNESS: I saw that. 4 BY MS. PARFITT: 5 Q Okay. You weren't one of those, were 6 you? 7 MS. BROWN: Objection to the form. 8 THE WITNESS: I'm not a statistician. 9 BY MS. PARFITT: 10 Q Okay. Well, but you use statistics in 11 your practice? 12 A I do. 13 Q Okay. Did anyone say you had to be a 14 statistician to sign on to that proposition? 15 A Well, I -- I thought I heard you say 16 statisticians. Maybe I -- I might have misheard. 17 I thought you said 800 statisticians. 18 Q I said there are about 800 statisticians 19 and other scientists that -- 20 A Oh, and other scientists. 21 Q -- yeah, that signed on to this. 22 A No, I didn't hear right. So I just -- 23 so I don't know what the criteria were for who 24 could sign or not sign. 25 Q Okay. You didn't sign on to it, though;</p>	<p style="text-align: right;">Page 309</p> <p>1 A Mm-hmm. 2 Q -- it is moving -- it states "Moving to 3 the World Beyond P" -- it's a special issue of The 4 American Statistician. The lead article calls for 5 abandoning the use of status -- statistically 6 significant, and offers much, not just one thing, 7 to replace it, written by Ron Wasserstein, Allen 8 Shirm, and Nicole Lazar. The coeditors of this 9 special issue summarize the content of the issue's 10 43 articles. 11 These articles -- and put this up 12 there -- discuss the use of p-values and 13 statistical significance that Johns Hopkins' 14 researchers may find beneficial, and it attaches 15 the full article, which is what's been marked as 16 Exhibit No. 17. 17 Do you see that? 18 A I do. 19 Q Okay. Did anyone share with you at 20 Johns Hopkins that their Clinical and 21 Translational Research group was disseminating the 22 article by Wasserstein, "Moving to a World Beyond 23 P < 0.05," and urging individuals not only to 24 abandon the use of statistical significance, but 25 to discuss the use of p-values and statistical</p>

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<p>1 significance with the researchers at Johns 2 Hopkins? 3 And that's a mouthful. So let me make 4 it really clear. 5 MS. BROWN: Let me object -- 6 MS. PARFITT: I move to strike the 7 question. 8 MS. BROWN: You're going to strike it? 9 MS. PARFITT: Yeah, let me strike it. 10 BY MS. PARFITT: 11 Q Were you aware, Dr. Diette, that the 12 division of Clinical and Translational Research 13 over at Hopkins had distributed to its scientists 14 this group of 43 articles, including the 15 Wassertine -- Wasserstein, for purposes of 16 educating them with regard to this concern over 17 the misuse of statistical significance? 18 MS. BROWN: I object to a complete 19 misrepresentation of the exhibit and to 20 foundation. 21 THE WITNESS: So I mean, there's a lot 22 of things, right. I'll try to answer as many as I 23 can. 24 So one is that I probably got something 25 because I'm -- I've been part of the ICTR, and I</p>	<p>1 read all 800, but I looked to see if there were 2 people from Hopkins in particular that signed it, 3 and I knew one of the two. 4 Q Okay. Let me show you what we'll have 5 marked as Exhibit No. 20. And I will represent to 6 you that it is a list of the 800 signatories that 7 joined together to support this movement to 8 abandon p-value in statistical significance. 9 (Diette Exhibit No. 20 was marked 10 for identification.) 11 MS. PARFITT: Again, Counsel, I 12 apologize. Apparently, we only have one copy of 13 this document. 14 MS. BROWN: So is it the blog soliciting 15 the signatures, or is it just the list? 16 MS. PARFITT: It is the list of 17 signatories. 18 MS. BROWN: Okay, that's fine. 19 BY MS. PARFITT: 20 Q Do you see that? 21 A I do. 22 Q Okay. Do you know an Elizabeth Ogburn? 23 A I don't. I saw her name on here, but 24 I -- I don't know her. 25 Q All right. Do you know Daniel</p>
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<p>1 use the resources, I'm one of the people who 2 helped to write the grant to get it funded, and 3 so -- like I get a zillion things that fly by. 4 I don't know if I saw this or not, but I 5 probably wouldn't have clicked on if it came 6 through like an e-mail because I had already seen 7 it, like, as part of this -- as part of the Bowman 8 deposition. 9 BY MS. PARFITT: 10 Q Mm-hmm. 11 A But other than that, I mean, I think 12 it's -- I think they're smart to do it. They 13 should always put stuff out there for people to 14 read. It doesn't mean that we're going to get rid 15 of p of 0.05. It doesn't mean we're going to get 16 rid of statistical significance. They're just 17 saying it's an interesting read. 18 Q Do you know any of the signatories to 19 this particular document? 20 A I found one. One that I know 21 personally, and I'm just trying to remember if 22 there was anybody else that I saw. 23 Q Well, let me show you what we'll have 24 marked as Exhibit No. 20. 25 A Yeah, so let me just say, so I didn't</p>	<p>1 Sharfenstein (phonetic)? 2 A Sharfstein, and I know him. Yeah. 3 Q Okay. Is that -- do you know anyone 4 else that might appear on that list? 5 A I don't know. I didn't read it. I 6 just -- I literally just did a word search for 7 "Hopkins," and I came up with like one person 8 whose name is Hopkins who works in England, and 9 another one, something Hopkins Institute, which is 10 not, and then two from Johns Hopkins. 11 Q Okay. When did you do this research? 12 A In the last week. I mean, after -- 13 after reading the Bowman deposition. 14 Q All right. So you read the Bowman 15 deposition, and then you -- what caused you then 16 to -- to go back and look at that or for that? 17 A Well, because it sounds like an 18 interesting topic, and, you know, who knows, maybe 19 one day it either will or won't change, but it's 20 an interesting thing to read about. And so I 21 wanted to just sort of see what -- what you guys 22 were driving at. And then since I saw that there 23 were 800 signatories, I just figured I would see 24 if there was anybody at Hopkins that was part of 25 it or not.</p>

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<p>1 Q Mm-hmm. And you found a couple of 2 people from Hopkins? 3 A Yeah, I found two. One I know, one I 4 don't. 5 Q All right. Again, you were not one of 6 the signatories? 7 A Still true, yeah. 8 Q Okay. Okay. What position does 9 Dr. Sharfstein hold within the University? 10 MS. BROWN: Objection. Speculation. 11 THE WITNESS: He's been in the 12 Department of Biostatistics, and I don't know 13 what -- what other ways to label what he -- what 14 his positions are. 15 BY MS. PARFITT: 16 Q Okay. From the time you saw the 17 discussion about statistical significance and a 18 movement away from that and did your bit of 19 research, did you ever call Dr. Sharfstein to talk 20 to him about it? 21 A Not yet. I'm hoping I'll just run into 22 him at some point and -- and ask him about that. 23 Q Is the -- is your interest strong enough 24 that you might reach out to him? 25 MS. BROWN: Objection to the form.</p>	<p>1 significance and p-values? 2 A Yeah, well, I'd say the real world, 3 right. And the real world -- 4 Q I'm sorry. You're in the real world? 5 A Real world, yeah. 6 Q Okay. And what's the real world doing? 7 A Well, the real world, if I want to write 8 a grant, I have to provide people with a sample 9 size estimate of what it is that I'm looking for, 10 and the sample size estimate is almost always 11 based on hypothesis testing. And you have to 12 declare a certain p-value that you find to be a 13 credible one. 14 So I can't just say, I've decided 15 because I read some editorial that I'm not going 16 to use a p-value of 0.05. That I'm still stuck 17 with 0.05 as a -- as an estimate. And so if I 18 want to have any success getting a grant, I'm 19 going to have to still use the rules that we've 20 used for years. 21 And if I publish a paper, I happened to 22 look because I thought it was curious, I went on 23 New England Journal's website -- 24 Q Yes. 25 A -- and they have an extensive list of</p>
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<p>1 What -- what interest are we talking about? 2 BY MS. PARFITT: 3 Q Interest in this science that you have 4 indicated yourself seems to be pretty important. 5 MS. BROWN: Objection. That misstates 6 his testimony by a lot. 7 THE WITNESS: So it -- it might be. I 8 mean, the -- the reason there's no urgency for me 9 to do it is that I still live in the world in 10 2019, and I'm still living in a world where 11 hypothesis testing is the rule and p-values are 12 part of what you're required to report if you're 13 going to publish a paper in a credible journal. 14 And so, you know, whether -- whether 15 this gets traction or not, you know, we'll see. I 16 don't know what the replacement is going to be. I 17 don't know if chaos will ensue. It's an 18 interesting topic to talk about, but it's sure not 19 ready for prime time. 20 So I think if I see Dan in the hall, I 21 might ask him about it, but there's no -- there's 22 no urgency to it. 23 BY MS. PARFITT: 24 Q So what's the world you're living in 25 with regard to the relevance of statistical</p>	<p>1 ways in order to represent your p-values and your 2 confidence intervals that you have to adhere to if 3 you want to publish your papers. You know, Nature 4 said that they're not going to change their rules 5 based on this. 6 So, anyway, so it's like it's -- that's 7 the world that we live in right now. If you want 8 to communicate about -- about clinical science, 9 then you're going to have to use the rules that 10 we've learned to -- that we've learned to use. 11 Q Do you know if the rules you've just set 12 forth are the rules that Dr. -- or, excuse me, 13 that Dr. Rothman and Sander Greenland, esteemed 14 epidemiologists, promote in their practice? 15 A I have no idea what they promote. 16 Q Well, you read the article in Nature, 17 didn't you? 18 A Yeah, but you said "their practice." I 19 don't even know what that is even. 20 Q Well, who is the author of the Nature 21 article? 22 A We're talking about the -- the 23 commentary? 24 Q That's right. 25 A Yeah. So it looks like Armhein,</p>

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<p style="text-align: right;">Page 318</p> <p>1 Greenland and McShane. Or maybe not. Maybe</p> <p>2 that's -- wait a minute, I could be wrong. No,</p> <p>3 it's -- it's those three.</p> <p>4 Q And again, you don't know -- do you know</p> <p>5 any of them? I know you don't know Dr. Greenland.</p> <p>6 Do you know any of the others?</p> <p>7 A I do not.</p> <p>8 Q Okay. So if I understand your opinion</p> <p>9 today, you still believe in the strength of a</p> <p>10 statistical significance versus not statistically</p> <p>11 significant?</p> <p>12 A It's --</p> <p>13 MS. BROWN: Objection to the form.</p> <p>14 THE WITNESS: It's still a factor to</p> <p>15 consider when either planning, conducting, or</p> <p>16 interpreting a study.</p> <p>17 BY MS. PARFITT:</p> <p>18 Q Okay. And do you still live in the</p> <p>19 world that there is a threshold of a p-value of</p> <p>20 0.05?</p> <p>21 A It depends.</p> <p>22 Q Well, what do you mean "it depends"?</p> <p>23 A I'm going to explain.</p> <p>24 Q Please.</p> <p>25 A So that's why I used the example of p at</p>	<p style="text-align: right;">Page 320</p> <p>1 took wasn't anything novel or different. I mean,</p> <p>2 I don't know at all what his plans are going</p> <p>3 forward, but he still works at the University</p> <p>4 where we still compete for NIH grants --</p> <p>5 Q Mm-hmm.</p> <p>6 A -- and I haven't seen any change in the</p> <p>7 NIH's posture on this, and I haven't seen any, you</p> <p>8 know, ground swell of support for just doing</p> <p>9 whatever you feel like in order to publish your</p> <p>10 paper.</p> <p>11 Q Well, are you suggesting that what</p> <p>12 Dr. Greenland and others and Dr. Wasserstein have</p> <p>13 suggested to do whatever you -- let me get your</p> <p>14 words -- shall -- yeah. Okay.</p> <p>15 MS. PARFITT: Tell you what, let's take</p> <p>16 a quick break. I want to find that part, and</p> <p>17 we'll get back. Let's take a quick break.</p> <p>18 THE VIDEOGRAPHER: The time is 2:44 p.m.</p> <p>19 We're going off the record.</p> <p>20 (Recess.)</p> <p>21 THE VIDEOGRAPHER: The time is 2:53</p> <p>22 p.m., and we're back on the record.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Dr. Diette, when we left just before the</p> <p>25 break, you said: "I haven't seen any ground swell</p>
<p style="text-align: right;">Page 319</p> <p>1 0.05, right? I could just say, I have decided</p> <p>2 that now I only want to do studies with six people</p> <p>3 in them, and I'll be happy to have a p-value of</p> <p>4 0.5. You'd have to wish me luck getting it</p> <p>5 published anywhere because it's not going to</p> <p>6 happen, right?</p> <p>7 So if I still want to do research and I</p> <p>8 still want to get it published, I'm going to have</p> <p>9 to pick a threshold for a p-value that's agreeable</p> <p>10 to the peer reviewers and to the editor. And it</p> <p>11 doesn't have to be 0.05. In some circumstances it</p> <p>12 might be 0.01. It might be even lower than that.</p> <p>13 But a -- but a p threshold is necessary, at least</p> <p>14 in our current era, if you want to be able to</p> <p>15 conduct and talk about your research.</p> <p>16 Q Do you -- do you think Dr. Sharfstein is</p> <p>17 going to now have difficulty having his scientific</p> <p>18 works published?</p> <p>19 MS. BROWN: Objection. Based on what?</p> <p>20 There's no foundation for that question.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q You can answer the question, Doctor.</p> <p>23 A Well, exactly that. So -- so Sharfstein</p> <p>24 has been involved in some of our research and some</p> <p>25 critical illness stuff, and the approach that we</p>	<p style="text-align: right;">Page 321</p> <p>1 of support for doing whatever you feel like in</p> <p>2 order to publish your paper."</p> <p>3 I'm not talking about the publication of</p> <p>4 papers. What I would like to know from you is, do</p> <p>5 you agree, though, when you were evaluating the</p> <p>6 consistency of evidence, that one should not</p> <p>7 disregard studies that are nonstatistically</p> <p>8 significant and give greater weight to those that</p> <p>9 are statistically significant?</p> <p>10 MS. BROWN: Objection to the form of the</p> <p>11 question.</p> <p>12 THE WITNESS: I hear two questions</p> <p>13 there, and the first part I agree with, and the</p> <p>14 second part, it depends.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. Do you agree that when you are</p> <p>17 evaluating and weighing evidence, studies, that</p> <p>18 you should evaluate studies the same whether they</p> <p>19 are statistically significant or not statistically</p> <p>20 significant?</p> <p>21 MS. BROWN: Objection to the form. In</p> <p>22 what context?</p> <p>23 THE WITNESS: I don't know what</p> <p>24 "evaluate the same" means. I mean, I think any --</p> <p>25 any study that you think should be evaluated</p>

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<p style="text-align: right;">Page 322</p> <p>1 should be evaluated, you know, as thoroughly as</p> <p>2 you can.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q When you're evaluating the consistency</p> <p>5 of studies, is it proper epidemiology to consider</p> <p>6 those studies whether or not they are</p> <p>7 statistically significant or nonstatistically</p> <p>8 significant?</p> <p>9 MS. BROWN: Objection to the form.</p> <p>10 THE WITNESS: It is. And I think, you</p> <p>11 know, regardless of what Dr. Rothman has written,</p> <p>12 you know, it's part of the information that's</p> <p>13 available to you, and I think to ignore it would</p> <p>14 be, you know, not in your best interest.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. And would you agree that one</p> <p>17 should not conclude there is no association or no</p> <p>18 difference just because a -- one study is</p> <p>19 statistically significant and another study is</p> <p>20 significant?</p> <p>21 MS. BROWN: Objection to the form.</p> <p>22 THE WITNESS: And I agree with you,</p> <p>23 especially because you used "just because."</p> <p>24 BY MS. PARFITT:</p> <p>25 Q All right. So maybe -- what do you</p>	<p style="text-align: right;">Page 324</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Okay. Now, let's turn to -- your chart,</p> <p>3 and specifically the studies that you set forth in</p> <p>4 your report on pages 13 and 14.</p> <p>5 And if you'd go to your report, 13 and</p> <p>6 14.</p> <p>7 A I'm sorry, I've got somebody else's</p> <p>8 thing here.</p> <p>9 Q That's okay.</p> <p>10 A Okay.</p> <p>11 Q Okay. You got there? All right.</p> <p>12 What I would like -- all right. So you</p> <p>13 have that in front of you, correct, sir?</p> <p>14 A I do.</p> <p>15 Q Okay. Now, what I'll have marked as --</p> <p>16 for demonstrative purposes is a chart that we have</p> <p>17 marked as Diette Exhibit 21.</p> <p>18 (Diette Exhibit No. 21 was marked</p> <p>19 for identification.)</p> <p>20 BY MS. PARFITT:</p> <p>21 Q And let me hand that to you.</p> <p>22 MS. BROWN: Counsel, can you give a</p> <p>23 representation for the record about what</p> <p>24 Exhibit 21 is?</p> <p>25 MS. PARFITT: Yes, I was about to do</p>
<p style="text-align: right;">Page 323</p> <p>1 mean?</p> <p>2 A No, it's a good sentence. I mean, I --</p> <p>3 it -- I think that over and over what we're</p> <p>4 talking about is that -- that you shouldn't be</p> <p>5 wedded to the idea that statistical significance</p> <p>6 is the only feature that you look at, but it</p> <p>7 doesn't mean that you don't look at it.</p> <p>8 And so when you say that, you know, if</p> <p>9 you were just to hold up two studies, and one was</p> <p>10 significant and the other one wasn't and -- that</p> <p>11 wouldn't -- you know, you wouldn't be curious</p> <p>12 enough. You would need to know more about those</p> <p>13 studies to reach the conclusion you do.</p> <p>14 So I think, you know, looking at the</p> <p>15 whole study, looking how it's built, looking how</p> <p>16 it's interpreted, all that's important.</p> <p>17 Q All right. So it would not be proper to</p> <p>18 conclude the two studies conflict just because one</p> <p>19 was significant and one was statistically</p> <p>20 significant.</p> <p>21 MS. BROWN: Objection. Misstates</p> <p>22 testimony.</p> <p>23 THE WITNESS: It -- not -- not by</p> <p>24 itself, but that is at least one indicator of</p> <p>25 something that's different about those studies.</p>	<p style="text-align: right;">Page 325</p> <p>1 that.</p> <p>2 MS. BROWN: Thank you.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q Dr. Diette, on pages 13 and 14, you</p> <p>5 have -- of your report, you have listed I believe</p> <p>6 25 case-control studies, 3 cohort studies and --</p> <p>7 is that correct?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q You've got 7 population studies on the</p> <p>11 back. That's on page 14. You have 25</p> <p>12 case-control -- hospital studies, rather, on</p> <p>13 page 14, and 25 studies on page 13. Is that</p> <p>14 correct?</p> <p>15 MR. LOCKE: Do you have a copy for --</p> <p>16 MS. PARFITT: Beg your pardon?</p> <p>17 MR. LOCKE: Do you have a copy for me,</p> <p>18 please?</p> <p>19 MS. PARFITT: Oh, Tom, I think we do,</p> <p>20 yeah.</p> <p>21 MR. LOCKE: Thank you. Is this a --</p> <p>22 does this come from a published --</p> <p>23 MS. PARFITT: No. Let me represent --</p> <p>24 no, let me represent that Exhibit No -- Exhibit 21</p> <p>25 is a demonstrative which lists all of the studies</p>

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<p style="text-align: right;">Page 326</p> <p>1 that Dr. Diette listed in his report on page 13 2 and 14 and has put them on a graph. 3 MS. BROWN: Who -- who put them on a 4 graph and what is the graph? 5 MS. PARFITT: Counsel -- 6 MS. BROWN: Well, I'm going to have an 7 objection to this document, and I just want to -- 8 MS. PARFITT: You can. You can object 9 to this -- 10 MS. BROWN: -- make sure I'm properly 11 objecting, because I don't know what it is, who 12 made it, based on what, and to the extent the 13 doctor needs the underlying studies to answer your 14 questions. We'll -- 15 MS. PARFITT: Counsel, no speaking 16 objections. 17 MS. BROWN: I just want to object to 18 this. 19 BY MS. PARFITT: 20 Q Dr. Diette -- 21 MS. PARFITT: I understand, Counsel. I 22 know what you're doing. 23 MS. BROWN: The name is Diette. 24 MS. PARFITT: Diette? 25 MS. BROWN: Diette.</p>	<p style="text-align: right;">Page 328</p> <p>1 MS. PARFITT: Yeah, there you go. 2 There you go, Doctor. 3 BY MS. PARFITT: 4 Q Doctor, I've handed you what's marked as 5 Exhibit 22. It is the -- an article by Patricia 6 Hartge dated 1983 in JAMA. Do you see that? 7 A I do. 8 Q Okay. And at the top of the study, she 9 has a table entitled "Estimated Relative Risk." 10 Do you see that? 11 A I do. 12 Q And I'll put this up on the ELMO. 13 MS. PARFITT: Okay. And it's hard to 14 see. We'll have to zero in there. There you go. 15 Okay. 16 BY MS. PARFITT: 17 Q You'll see on your chart you had listed 18 for Hartge, 1983, a relative risk of 0.7 with a 19 confidence interval of 0.40 to 1.10. 20 Do you see that? 21 A Uh -- 22 Q Look at your -- 23 A I do, yep. 24 Q -- on page 14. 25 Okay. Now, look at the table of the</p>
<p style="text-align: right;">Page 327</p> <p>1 MS. PARFITT: Diette. 2 BY MS. PARFITT: 3 Q I'm sorry, Dr. Diette. I'm not doing it 4 to annoy you. 5 A You've had it -- you've had it right all 6 day. You're good. 7 Q Thank you. Thank you. I appreciate 8 that. 9 What I will represent to you, and you 10 can track it, Dr. Diette, that Exhibit No. 21 11 represents the sales studies you selected for 12 purposes of your expert report. It lists them 13 study by study. It plots them on a forest plot on 14 the right-hand side. 15 Do you see that? 16 A I do. 17 Q Okay. And I'll represent that we took 18 your relative risks and confidence intervals, and 19 simply extracted those and put them on Exhibit 21 20 with one exception. 21 What I'd like you to do is look at 22 Hartge. And we will have that marked as 23 Exhibit 22. 24 (Diette Exhibit No. 22 was marked 25 for identification.)</p>	<p style="text-align: right;">Page 329</p> <p>1 Hartge study under "Genital Talc Use." 2 Do you see that? 3 A I do. 4 Q Okay. And do you see where Dr. Hartge 5 reports that the relative risk for genital use 6 talcum powder is not what you have as 0.7, but 2.5 7 with a confidence interval of 0.7 to 10. 8 Do you see that? 9 A I do. 10 Q All right. So that would be an error in 11 your chart; is that correct? 12 MS. BROWN: Objection. 13 Doctor, take as long as you need to look 14 at what counsel is asking you about. 15 And -- 16 MS. PARFITT: Counsel -- 17 MS. BROWN: -- Counsel, do you mean 18 to -- 19 MS. PARFITT: Counsel -- 20 MS. BROWN: -- misrepresent the 21 paragraph? 22 MS. PARFITT: No, Counsel. And, listen, 23 if the Doctor doesn't have any questions -- he's a 24 very intelligent man as we've seen today -- 25 MS. BROWN: I know, but what you're</p>

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<p style="text-align: right;">Page 330</p> <p>1 saying is not right. 2 MS. PARFITT: Counsel, that's it. No. 3 I'm sorry. 4 MS. BROWN: Are you intentionally 5 misrepresenting what's in the paper? 6 MS. PARFITT: Counsel, if you heard my 7 question -- I think Dr. Diette understands the 8 question. 9 BY MS. PARFITT: 10 Q Dr. Diette, we have on the table a 11 genital use, which is 2.5 with a confidence 12 interval of 0.7 to 10. 13 Do you see that? 14 A Yeah, I'm sorry. Can you give me just 15 one second? 16 Q Okay. Of course I can. 17 A Thank you. (Peruses document.) 18 Yeah, I'm with you. 19 Q Okay. And the only correction I -- I 20 wish to make is that, instead of the 0.70 that you 21 have for Hartge, it should be 2.5 -- 22 MS. BROWN: Objection. 23 BY MS. PARFITT: 24 Q -- for the genital -- 25 MS. PARFITT: Let me finish, Counsel.</p>	<p style="text-align: right;">Page 332</p> <p>1 MS. BROWN: Okay. Then let him -- 2 MS. PARFITT: I just don't want you 3 coaching -- 4 MS. BROWN: -- answer the question. 5 MS. PARFITT: -- and touching the paper 6 and pointing at things. 7 MS. BROWN: You are intentionally 8 misreading this document. 9 BY MS. PARFITT: 10 Q Doctor -- all right, Dr. Diette, you're 11 the one I'm interested in hearing from, to be 12 perfectly candid. 13 My question is, are the -- is the 14 relative risk that you have listed for Hartge 15 0.70, or should it be 2.5? 16 A You know, the -- the study report is 17 really tough I think to decide that either one of 18 them is ideal. And for a couple of reasons, and 19 one is just because this -- this genital with an 20 asterisk, it isn't literally just genital 21 application. It includes sanitary napkins. 22 And you can see in a lot of the studies 23 that people have sort of broken out sanitary 24 napkin use separate from like perineal 25 application.</p>
<p style="text-align: right;">Page 331</p> <p>1 BY MS. PARFITT: 2 Q -- for the genital use of talc. Do you 3 agree with that? 4 MS. BROWN: Objection to the form. 5 THE WITNESS: So, maybe. I'm just 6 trying to think about how I got -- 7 BY MS. PARFITT: 8 Q Sure. 9 A -- got here. Because the -- you know, 10 the text says that it's -- there were ten users, 11 so I guess like seven cases and three controls. 12 Q Mm-hmm. 13 A It said -- specifically mentioned use on 14 sanitary napkins, underwear, or the genital area. 15 But then it says -- but estimated is 16 2.5, but the small number of exposed women yielded 17 an unreliable estimate. So I -- 18 MS. BROWN: It's -- 19 THE WITNESS: Yeah -- 20 MS. PARFITT: You don't have to show the 21 doctor. 22 MS. BROWN: Do you want the truth on the 23 record, or do you want -- 24 MS. PARFITT: You know, I really do want 25 the truth.</p>	<p style="text-align: right;">Page 333</p> <p>1 And so, you know, that's not an ideal 2 measure for this -- this chart either. I mean, I 3 get your point, the all over is something else. 4 But there's at least -- you know, there's more 5 than ten people at least in that particular -- 6 that particular row. So I -- I'm not sure if 7 either of these is great, but they -- 8 Q Well, the analysis you went through, did 9 you go through that analysis for each and every 10 one of the studies that you listed when you made a 11 decision as to which odds ratio to select? 12 A I did. 13 Q You did. 14 A I mean, I tried to pick the one that -- 15 that fit the best. 16 Q Okay. And is the one that fits the best 17 for Hartge the 0.70, or is the one that fits the 18 best for Hartge the 2.5? 19 MS. BROWN: Objection to the form. 20 THE WITNESS: So I don't know. I mean 21 other than the fact that you've got the word 22 "genital" there, I mean "all over" is kind of 23 confusing, right, because it doesn't say like "all 24 over except the genitals," right. 25 And so that's where it gets kind of</p>

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<p>1 confusing is how you -- it's not a great study, 2 right. I mean, I'm not saying the study is not 3 great. I'm saying the report of the study doesn't 4 really tell us everything that you could really 5 wish to know. 6 BY MS. PARFITT: 7 Q So would you like to keep your chart 8 with the 0.70, or do you think the chart should be 9 modified to say 2.5? 10 MS. BROWN: Objection to the form. 11 THE WITNESS: I mean, I'd be happy to 12 put both rows there and just with an asterisk, and 13 explain, you know, what each one of those is. 14 BY MS. PARFITT: 15 Q Okay. Would you -- have you done that 16 for all the other studies that you've listed here, 17 wherein there may be data for sanitary napkins and 18 data for genital use and data for cornstarch? Did 19 you go through that analysis? 20 MS. BROWN: Objection to the form. 21 THE WITNESS: So, for this table I 22 haven't, but I have gone through all the sanitary 23 napkin findings that I can. And that's one of the 24 things you'll find in my handwritten notes from 25 the -- from the prior case.</p>	<p>1 you did, where is that contained in your report? 2 MS. BROWN: And you should feel free to 3 answer both questions since counsel cut you off. 4 THE WITNESS: I have no idea about what 5 you mean by where it is in the report. 6 BY MS. PARFITT: 7 Q Well, I only have RRs here. I have a 8 table. No analyses of the different case 9 controls. Just a table of their relative risks. 10 So, you've now gone through an analysis 11 of the Hartge case and said, You know, maybe this 12 is what we should have extracted, maybe we should 13 have looked at this, but I used my judgment and 14 put the 0.7. 15 And what I'm asking is, is that analyses 16 that you just did for us on the record the kind of 17 analysis that you did for all the other studies? 18 And if it was, where in the 51 pages of your 19 report or this chart have you included that 20 information? 21 MS. BROWN: Objection. Completely 22 misstates his testimony, as well as the article, 23 as well as the report, as well as the chart. 24 THE WITNESS: Let me just see. So 25 obviously it's not -- it's not documented, but I</p>
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<p>1 In terms of cornstarch, that's a 2 different question. 3 BY MS. PARFITT: 4 Q And, Doctor, I -- 5 MS. BROWN: Wait, he needs to finish. 6 He's got to -- 7 BY MS. PARFITT: 8 Q Doctor, that's really not my question. 9 MS. BROWN: No, no, no, no, no, he -- 10 BY MS. PARFITT: 11 Q My question is this -- 12 MS. BROWN: Counsel. 13 MS. PARFITT: Counsel. 14 BY MS. PARFITT: 15 Q My question is -- 16 MS. BROWN: He has to finish the 17 question. 18 BY MS. PARFITT: 19 Q You're not answering my question. Mine 20 is a very simple one. 21 My question was -- if you'll be patient 22 with me, my question was: The analysis that 23 you've just talked about that you're going through 24 with Hartge, did you go through a similar analysis 25 for each and every one of these studies; and if</p>	<p>1 think part of what I'm trying to do is communicate 2 what the -- what the risks are that were reported 3 and what their confidence bounds were. 4 And so, you know, the papers stand for 5 themselves. They all exist. They're all cited. 6 We can look at anything we want. 7 I think in terms of the cornstarch 8 issue -- 9 BY MS. PARFITT: 10 Q Doctor, I'm not asking about -- 11 MS. BROWN: Stop cutting him off. 12 BY MS. PARFITT: 13 Q -- the cornstarch. We can talk about 14 that later. I'm not talking about cornstarch. 15 MS. BROWN: You cannot continue to cut 16 him off, or we'll have to call the Judge. 17 MS. PARFITT: I don't have a question 18 about cornstarch. 19 MS. BROWN: He's answering your 20 question. 21 MS. PARFITT: He is not. 22 MS. BROWN: You have to let him answer 23 or we have to call the Judge. You are 24 violating -- 25 MS. PARFITT: You can do it in your</p>

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<p style="text-align: right;">Page 338</p> <p>1 direct.</p> <p>2 MS. BROWN: No, you have to let him</p> <p>3 answer the question or --</p> <p>4 MS. PARFITT: Counsel.</p> <p>5 MS. BROWN: We're going off the record.</p> <p>6 MS. PARFITT: Do you want to go -- we'll</p> <p>7 go off the record right now.</p> <p>8 MS. BROWN: Yeah, let's go. Fine. Do</p> <p>9 we need to call the Judge? You have to let him</p> <p>10 answer.</p> <p>11 MS. PARFITT: We'll call her. We'll</p> <p>12 call her.</p> <p>13 THE VIDEOGRAPHER: The time is 3:09 p.m.</p> <p>14 We're going off the record.</p> <p>15 (A discussion was held off the record.)</p> <p>16 THE VIDEOGRAPHER: The time is</p> <p>17 3:10 p.m., and we're back on the record.</p> <p>18 MS. PARFITT: Thank you.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q And, Dr. Diette, all I'm trying to -- to</p> <p>21 ask, and obviously very poorly, is the analysis</p> <p>22 that you just discussed that you went through with</p> <p>23 Hartge, as we sat here today and you did it on the</p> <p>24 record, did you do that for all the other studies?</p> <p>25 A I tried to.</p>	<p style="text-align: right;">Page 340</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Correct?</p> <p>3 A I did.</p> <p>4 Q Okay. And my last question is, is that</p> <p>5 the position you wish to take today?</p> <p>6 MS. BROWN: Objection to the form.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Or would you modify that and use a</p> <p>9 different relative risk? That's all.</p> <p>10 A I don't --</p> <p>11 MS. BROWN: Objection.</p> <p>12 THE WITNESS: I don't think anybody is</p> <p>13 well served by looking at this other number, other</p> <p>14 than if you're just trying to make a point and</p> <p>15 be -- you know, for a plaintiff or something to</p> <p>16 look at this 2.5.</p> <p>17 I think if you take this one that says</p> <p>18 there's a small number of exposed women, ten</p> <p>19 people, you know, that yields an unreliable</p> <p>20 estimate. I mean, somebody should fuss about that</p> <p>21 too. So that's not -- that's not an ideal</p> <p>22 measure.</p> <p>23 If it helps, we can put them on the</p> <p>24 table, and it wouldn't really change things,</p> <p>25 right. You've got confidence bounds from 0.7 to</p>
<p style="text-align: right;">Page 339</p> <p>1 Q Okay. And so you had to make</p> <p>2 determinations as to what relative risks to</p> <p>3 extract from those studies, correct?</p> <p>4 MS. BROWN: Objection to the form.</p> <p>5 THE WITNESS: I -- I had to work with</p> <p>6 what they reported.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Okay. And just like Hartge, they</p> <p>9 reported different pieces of information:</p> <p>10 Diaphragms used, no diaphragm, all over, genital,</p> <p>11 legs, feet, correct?</p> <p>12 A Correct.</p> <p>13 Q And you had to decide what was the most</p> <p>14 appropriate data to pull from those studies to</p> <p>15 include on your chart for relative risks, correct?</p> <p>16 A For the most --</p> <p>17 MS. BROWN: Objection to the form.</p> <p>18 THE WITNESS: Yes, of course.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q Okay. So my question to you is, you</p> <p>21 chose for the Hartge, based upon that analysis, to</p> <p>22 use the -- any talc mentioned, which gave us a</p> <p>23 relative risk of 0.7, as opposed to genital, which</p> <p>24 would have represented a 2.5 risk.</p> <p>25 MS. BROWN: Objection to the form.</p>	<p style="text-align: right;">Page 341</p> <p>1 10. I mean, that's an enormous confidence value.</p> <p>2 So there's not a lot of information from those ten</p> <p>3 people.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q And the reason I ask as well, as you</p> <p>6 said earlier on in your deposition, you did not</p> <p>7 know for all these studies their sample size.</p> <p>8 A Oh, no, no, no. I didn't memorize it,</p> <p>9 but I've got all the studies, and it's a piece of</p> <p>10 cake, we can just go look at them and look at the</p> <p>11 sample size. I didn't want to, like -- I didn't</p> <p>12 want to, like, make -- this is already a long</p> <p>13 enough report. I don't need to put every bit of</p> <p>14 data from every study in it to have it make sense</p> <p>15 to me.</p> <p>16 Q So somewhere you have all the sample</p> <p>17 sizes pulled together for the various cases and</p> <p>18 controls for each one of these studies?</p> <p>19 A It's in every one of the studies.</p> <p>20 Q I know it's in each and every one of the</p> <p>21 studies, but did you document it on any kind of</p> <p>22 chart or anything like that?</p> <p>23 A For what?</p> <p>24 Q So that you could tell someone like me</p> <p>25 and the Court why you chose the data that you did.</p>

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<p>1 A We can just look at the studies. If I</p> <p>2 documented the sample size next to each one of</p> <p>3 these, it wouldn't tell you why I picked this</p> <p>4 particular relative risk.</p> <p>5 Q It would -- it would not offer valid</p> <p>6 information as to the relevance of those relative</p> <p>7 risks?</p> <p>8 A Oh, my gosh. I mean if you were</p> <p>9 interested in it, I could find it for you. It</p> <p>10 wasn't -- it wasn't important for me to</p> <p>11 communicate what I was trying to communicate.</p> <p>12 Q No, I -- it's a different question.</p> <p>13 Is sample size important when one is</p> <p>14 doing an analysis of a scientific study?</p> <p>15 A Yeah, that's why it's in the paper.</p> <p>16 Q Okay. Because if the sample size is too</p> <p>17 small, it may be underpowered; is that correct?</p> <p>18 MS. BROWN: Objection.</p> <p>19 THE WITNESS: Well, I don't know. I</p> <p>20 mean, if we're going to do power now, I think</p> <p>21 that's going to be a different -- a different</p> <p>22 conversation.</p> <p>23 The sample size being small can have all</p> <p>24 kinds of -- all kinds of impact. This to me is</p> <p>25 actually the most generous way to look at these</p>	<p>1 doesn't change anything about this exercise.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Okay. Well, I didn't select Hartge.</p> <p>4 You selected Hartge.</p> <p>5 A Well, I selected it because it exists.</p> <p>6 I mean, I -- my -- my goal was to find all the</p> <p>7 studies that exist.</p> <p>8 Q Okay.</p> <p>9 A I mean, I didn't invent it, right? I</p> <p>10 just -- I just looked at --</p> <p>11 Q Well, I just didn't want the record to</p> <p>12 reflect that I was selecting your data.</p> <p>13 A No, but you -- it sounds like you would</p> <p>14 prefer me to use that 2.5 from the ten people,</p> <p>15 instead of the 0.7 from the nearly hundred people.</p> <p>16 Q I have --</p> <p>17 A And I'm happy to look at them both. I</p> <p>18 mean they both tell us some information. It's not</p> <p>19 like, you know, one is ideal and the other isn't.</p> <p>20 But it really doesn't change the basic premise</p> <p>21 here.</p> <p>22 Q All right. So on my chart I have them</p> <p>23 both. I have 0.7 and 2.5. Do you see that?</p> <p>24 A Um --</p> <p>25 Q Right at the bottom there, "Genital use"</p>
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<p>1 data, rather than picking at the same size. I</p> <p>2 mean, I can do that too, right? I can say, This</p> <p>3 is a crummy study because it's got 23 people, or</p> <p>4 this is crummy one -- that wasn't my goal. It</p> <p>5 wasn't to sort of tear down the -- the</p> <p>6 case-control studies.</p> <p>7 I was trying to have a balanced approach</p> <p>8 here, I think unlike the plaintiffs' experts, and</p> <p>9 I wasn't trying to say that this one particular</p> <p>10 design is awful and the other one is good. I was</p> <p>11 just trying to represent something about it in</p> <p>12 order to summarize it and communicate a point.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Okay. And your balanced approach was to</p> <p>15 take the lower, the 0.7 relative risk, rather than</p> <p>16 the 2.5 relative risk.</p> <p>17 A Oh, my goodness.</p> <p>18 MS. BROWN: Objection to the form.</p> <p>19 THE WITNESS: I -- I think -- I mean, I</p> <p>20 think this little article, that doesn't even fit</p> <p>21 on an entire page, gives us so little information</p> <p>22 about what to do, and I think my point about there</p> <p>23 being ten people that provide a relatively</p> <p>24 uninformative risk, it's not great. If you want</p> <p>25 to use it, you're welcome to, but it doesn't -- it</p>	<p>1 and "Any talc use." Do you see that?</p> <p>2 A I do.</p> <p>3 Q Okay. All right. So as I appreciate</p> <p>4 your testimony, you had selected 25 population</p> <p>5 case controls, 7 hospital -- and 7 hospital case</p> <p>6 controls, correct?</p> <p>7 MS. BROWN: Objection.</p> <p>8 BY MS. PARFITT:</p> <p>9 Q Do I have the numbers right?</p> <p>10 A I wasn't listening. I'm sorry.</p> <p>11 MS. BROWN: Look at the realtime. I</p> <p>12 just think you misspoke. You said seven hospitals</p> <p>13 twice. Is that what you meant?</p> <p>14 BY MS. PARFITT:</p> <p>15 Q As I appreciate your testimony, you</p> <p>16 selected -- no, this is populate -- 25 population</p> <p>17 case controls and 7 hospital case controls. I</p> <p>18 said it twice. Correct?</p> <p>19 A That's correct.</p> <p>20 Q Okay. And that formed the basis for</p> <p>21 your selection of case studies, correct?</p> <p>22 MS. BROWN: Objection to the form.</p> <p>23 THE WITNESS: Case-control studies.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Case-control studies.</p>

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<p style="text-align: right;">Page 346</p> <p>1 A Correct.</p> <p>2 Q Yes. Okay.</p> <p>3 Now, looking at the chart, which is 21,</p> <p>4 what is the point estimate -- wait.</p> <p>5 What I would like you to do, rather, I</p> <p>6 would like you to circle the point estimate for</p> <p>7 every study that exceeds -- that has a 1.0.</p> <p>8 MS. BROWN: Objection. Based on the</p> <p>9 document you created as 21?</p> <p>10 MS. PARFITT: Which is identical to the</p> <p>11 doctor's document, with the exception of I put two</p> <p>12 numbers for Hartge.</p> <p>13 MS. BROWN: You put two numbers for</p> <p>14 Moorman too.</p> <p>15 MS. PARFITT: Before and after 2014,</p> <p>16 correct?</p> <p>17 MS. BROWN: Nope, Moorman is 2009. You</p> <p>18 have -- you've broken out Moorman by race.</p> <p>19 MS. PARFITT: I did.</p> <p>20 MS. BROWN: So I mean, my point here is</p> <p>21 just if you wanted to use his report, he's happy</p> <p>22 to answer your questions, but --</p> <p>23 MS. PARFITT: He did it -- but he did it</p> <p>24 too.</p> <p>25 MS. BROWN: Okay. That's fine.</p>	<p style="text-align: right;">Page 348</p> <p>1 to be hard for me to read it off of your figure</p> <p>2 because I don't know, like -- like, the Harlow and</p> <p>3 Weiss one -- what is wrong with that one? Or is</p> <p>4 it --</p> <p>5 MS. BROWN: That looks wrong, doesn't</p> <p>6 it?</p> <p>7 THE WITNESS: No, it's Harlow and Weiss</p> <p>8 versus Harlow.</p> <p>9 So what am I circling? I'm circling</p> <p>10 the -- the -- on the forest plot?</p> <p>11 BY MS. PARFITT:</p> <p>12 Q On the forest plot, if you would be kind</p> <p>13 enough to circle every relative risk where the</p> <p>14 point estimate was 1.0 or above.</p> <p>15 A Oh, I did it wrong.</p> <p>16 Q That's all right.</p> <p>17 A Sorry. I'm circling the ones that</p> <p>18 are -- do you have another -- another copy of</p> <p>19 this?</p> <p>20 MS. MILLER: You can have mine.</p> <p>21 MR. LOCKE: I didn't --</p> <p>22 MS. PARFITT: I'm sorry. I'm sorry,</p> <p>23 Tom?</p> <p>24 MR. LOCKE: I just couldn't hear -- you</p> <p>25 trailed off at the end.</p>
<p style="text-align: right;">Page 347</p> <p>1 MS. PARFITT: It's on his chart.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q I didn't do anything -- the only</p> <p>4 modification I made to your chart, Doctor, is</p> <p>5 Hartge, and there I kept your 0.70 and added the</p> <p>6 genital 2.5.</p> <p>7 And what I'd like you to do is circle in</p> <p>8 that document every point estimate or odds ratio</p> <p>9 that is 1.0 or above.</p> <p>10 A 1.0 or higher?</p> <p>11 Q That's right.</p> <p>12 MS. BROWN: Objection to the exercise.</p> <p>13 And, Doctor, if you need the articles,</p> <p>14 we'll give them to you.</p> <p>15 THE WITNESS: So just as an example, if</p> <p>16 we look at Jordan 2007, which has an odds ratio of</p> <p>17 1.00 --</p> <p>18 BY MS. PARFITT:</p> <p>19 Q Mm-hmm.</p> <p>20 A -- you find that one that would be</p> <p>21 interesting for me to circle.</p> <p>22 Q If it has a 1.0, I'd like you to circle</p> <p>23 it.</p> <p>24 A Sure.</p> <p>25 So in terms of your -- like, it's going</p>	<p style="text-align: right;">Page 349</p> <p>1 MS. PARFITT: Sure.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q You have -- and maybe I can shorten this</p> <p>4 for you, how about that, in the interest of time.</p> <p>5 A Your call.</p> <p>6 Q We have -- thank you. I appreciate</p> <p>7 that.</p> <p>8 We've got about 32 studies here. How</p> <p>9 many of those studies reflect an odds ratio</p> <p>10 greater than 1.0?</p> <p>11 MS. BROWN: For a relative risk?</p> <p>12 MS. PARFITT: Correct.</p> <p>13 THE WITNESS: I don't know what to do</p> <p>14 with Moorman, because it's one study, right. Two</p> <p>15 different odds ratios.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q Mm-hmm.</p> <p>18 A But it looks like above the dotted line,</p> <p>19 it's -- there's 24 studies, I guess, and then down</p> <p>20 below it, there's -- one, two, three, four,</p> <p>21 five -- there's 5 that are above 1.0, and you said</p> <p>22 above 1.0 this time, before you said --</p> <p>23 Q Above -- I did, above 1.0.</p> <p>24 A Because the including an odds ratio of</p> <p>25 1.00 is evidence of something above 1.0 would</p>

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<p>1 be --</p> <p>2 Q Right. So we're doing above 1.0.</p> <p>3 A Okay.</p> <p>4 Q You pointed that out, and you're right.</p> <p>5 A Yeah. So have I done it? There's one,</p> <p>6 two, three, four -- well, I guess Hartge is --</p> <p>7 one, two, three, four, five --</p> <p>8 Q Sure.</p> <p>9 A -- there's five down below the dotted</p> <p>10 line, and there were --</p> <p>11 Q Okay. And if you can just identify</p> <p>12 those where the point estimate does not exceed --</p> <p>13 it's not above 1.0.</p> <p>14 MS. BROWN: Counsel, can you represent,</p> <p>15 on the record, what this second up from the bottom</p> <p>16 is?</p> <p>17 MS. PARFITT: Sure. Hartge and Stewart,</p> <p>18 '94.</p> <p>19 MS. BROWN: Underneath that.</p> <p>20 MS. PARFITT: Wong.</p> <p>21 MS. BROWN: No, above -- what is the</p> <p>22 entry above Wong?</p> <p>23 MS. PARFITT: Oh, in his table --</p> <p>24 THE WITNESS: Oh, that too.</p> <p>25 MS. PARFITT: In his table he had RR</p>	<p>1 that those studies have a relative risk in excess</p> <p>2 of 1.0 demonstrate a positive result?</p> <p>3 MS. BROWN: Objection to the form.</p> <p>4 THE WITNESS: So some -- some of those,</p> <p>5 yes, and some of those, no.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q All right. Would it be fair to say that</p> <p>8 they're certainly trending above the null; is that</p> <p>9 correct?</p> <p>10 MS. BROWN: Objection to the form.</p> <p>11 THE WITNESS: Not necessarily. I'm just</p> <p>12 trying to imagine like -- I think I understand why</p> <p>13 you're doing this -- but I'm just trying to</p> <p>14 imagine like standing in front of colleagues like</p> <p>15 with the Tzonou one and say, I've decided that a</p> <p>16 relative risk of 1.05 is a positive risk.</p> <p>17 I mean, you can only guess so close to</p> <p>18 1.0. I mean, 1.0 is basically null, right?</p> <p>19 There's no -- there's no effect. So you can hope</p> <p>20 for, but you're rarely going to get a 1.00. So if</p> <p>21 you get like a 1.01, 1.02, 1.03, those are</p> <p>22 basically 1.0.</p> <p>23 I mean, you can -- you can say -- try to</p> <p>24 make some point to somebody, Oh, it's a little bit</p> <p>25 above 1.0; therefore, it's a positive association.</p>
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<p>1 0.03, RR 0.05. It was just extracted from his</p> <p>2 table.</p> <p>3 MS. BROWN: Oh, it's the second Hartge</p> <p>4 and Stewart.</p> <p>5 MS. PARFITT: Yeah.</p> <p>6 THE WITNESS: And so you want where just</p> <p>7 the midpoint is above the number 1.0?</p> <p>8 BY MS. PARFITT:</p> <p>9 Q Correct.</p> <p>10 A So Cramer, Harlow, Harlow, Chen, Cramer,</p> <p>11 Purdie, Chang, Cook, Green, Godard, Cramer, Ness,</p> <p>12 Mills, Cramer, Gates, Merritt; the two odds ratios</p> <p>13 for Moorman, Wu, Rosenblatt, Kurta, Kotsopoulos,</p> <p>14 Wu, Cramer, Schildkraut; and then one of the two</p> <p>15 Hartge's, Whittemore --</p> <p>16 Q And are you circling those, Doctor?</p> <p>17 A I'm not, no.</p> <p>18 Q Okay. If you could do that because</p> <p>19 we'll attach it as an exhibit. Sorry.</p> <p>20 A Should I just finish saying them --</p> <p>21 Q Sure.</p> <p>22 A -- and then go back and do it?</p> <p>23 So Rosenblatt, Tzonou, and that's it.</p> <p>24 So -- (circling studies.) Okay.</p> <p>25 Q Okay. What does the -- does the fact</p>	<p>1 But other than this setting, you're going to get</p> <p>2 laughed out of the room. I mean, this is -- this</p> <p>3 is a 1.05. So, you know, that's -- you call it</p> <p>4 what you want. I don't call that a positive</p> <p>5 finding.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Okay. Now, what I'd like you to do is</p> <p>8 look at the confidence intervals for each one of</p> <p>9 those studies, and circle where the confidence</p> <p>10 interval shows a relative risk of 1.2.</p> <p>11 MS. BROWN: Objection to the form of the</p> <p>12 question.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q And again, if you will just circle</p> <p>15 those.</p> <p>16 A I -- I think you'd be better off drawing</p> <p>17 a line, right. Because it -- I mean, this scale</p> <p>18 here isn't really -- like there's no vertical</p> <p>19 scale that's labeled here. Right. So you've got</p> <p>20 1.0, 1.1 and 1.2. I mean if you want, I think you</p> <p>21 ought to just take a ruler and run it up from 1.2.</p> <p>22 Q Why don't you just go ahead and identify</p> <p>23 them, if you will, and we can go ahead and do</p> <p>24 that. Let's see.</p> <p>25 A Well, like I can --</p>

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<p>1 Q My question is just simply this: Would 2 you identify all studies where the confidence 3 interval is 1.2 or higher? 4 MS. BROWN: Objection to the form. 5 BY MS. PARFITT: 6 Q And you can just circle them. 7 A And it doesn't have to mean anything to 8 me, right? 9 Q Nope. Just circle anything where the 10 confidence interval is above a 1.2. 11 A So where the confidence interval 12 includes 1.2? 13 Q 1.2, correct. 14 A Or where it's above 1.2? 15 Q It's above 1.2. 16 MS. BROWN: The entire interval? 17 THE WITNESS: Well, so there's not many, 18 right? So there's one -- 19 BY MS. PARFITT: 20 Q You understand that it includes 1.2? 21 A I heard -- oh, that's different, 22 because there's only one where it's above 1.2. 23 Q It includes the 1.2. 24 A Or two that are above it. 25 So the two that are above it, don't</p>	<p>1 was inconsistent. 2 Q And that aspect -- 3 MS. BROWN: Are you looking at the 4 report? 5 THE WITNESS: Yeah. 6 BY MS. PARFITT: 7 Q -- was with regard to population study 8 versus hospital-based studies? 9 A Well, I think I made a comment about 10 both, right? 11 Q And if I can summarize your testimony, 12 but feel free to look, but your testimony from the 13 report -- or your writings and your report suggest 14 that the case-control studies are inconsistent, 15 and you focus on the fact that the hospital-based 16 controls were inconsistent with the population- 17 based controls. 18 A That's one -- one of the areas of 19 inconsistency. 20 Q Okay. And you base that opinion on the 21 fact that there -- the hospital-based studies were 22 not statistically significant, but the 23 population-based studies were statistically 24 significant; is that correct? 25 MS. BROWN: Objection to the form.</p>
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<p>1 include it, right, so we got to start over. 2 Q Everywhere -- sure. You go ahead and do 3 it. Everywhere where the confidence interval is 4 above -- includes 1.2. 5 A That's all right. I'm just going to put 6 a little asterisk next to them, because I already 7 made a mark -- 8 Q Sure, that's fine. 9 A -- next to the ones that are above 1.2. 10 Okay. 11 Q Okay. Let's go ahead and just put this 12 here. I appreciate that. 13 Okay. Here we go. Let's see here. 14 Okay. So let's just stay with that one 15 here for a moment. Let me give you -- give you a 16 blank one here for a moment. Is that all right? 17 So you have something in front of you. 18 A Sure. 19 Q Okay. All right. 20 Dr. Diette, looking at the chart that we 21 just talked about, you have described in your 22 report that the case-control studies are 23 inconsistent. Is that your testimony? 24 A I think we should look literally at what 25 I wrote, because I talked about one aspect that</p>	<p>1 THE WITNESS: That's one piece of 2 evidence, right. So one piece of evidence is that 3 the hospital-based ones, none of them were 4 statistically significant, and some of the 5 population-based ones were. 6 BY MS. PARFITT: 7 Q All right. And because you had some of 8 the population-based studies, you found 9 inconsistent because the confidence intervals were 10 not -- were such that they were not statistically 11 significant; is that correct? 12 A That's a -- 13 MS. BROWN: Objection to the form. 14 THE WITNESS: And as before, that's a 15 piece of -- a piece of the information here. 16 BY MS. PARFITT: 17 Q Okay. I've reviewed your report. Other 18 than the distinction between the statistical 19 significance of studies versus the nonstatistical 20 significance of studies, how else did you discern 21 that they were different and not consistent? 22 A Well, I have a section on consistency. 23 So it -- there's other things about these studies 24 that are inconsistent. 25 So, for example, the -- the</p>

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<p style="text-align: right;">Page 358</p> <p>1 dose-response relationships are all over the</p> <p>2 place. So that I found to be an inconsistency.</p> <p>3 The findings about certain kinds of ovarian</p> <p>4 cancers, some showed a particular cell type and</p> <p>5 some -- some didn't.</p> <p>6 Let me just --</p> <p>7 Q Let me ask you --</p> <p>8 MS. BROWN: Wait, I don't think he's</p> <p>9 finished.</p> <p>10 MS. PARFITT: No. Let's just make sure.</p> <p>11 THE WITNESS: I think we've said it, but</p> <p>12 I want to make it clear, right, because we were --</p> <p>13 we were really just sort of focused very -- very</p> <p>14 much on population-based and hospital-based case</p> <p>15 controls.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q That's right.</p> <p>18 A But I think the fact that there is</p> <p>19 basically, you know, not a signal from the cohort</p> <p>20 studies is an inconsistency with studies of</p> <p>21 another design, so another form of inconsistency.</p> <p>22 I think that -- and what I've tried to</p> <p>23 say here, right, because I think -- I think some</p> <p>24 of these Hill criteria, it's hard to -- hard to</p> <p>25 keep every -- every comment you want under one</p>	<p style="text-align: right;">Page 360</p> <p>1 like that. So I'm -- that's more inconsistency.</p> <p>2 Q Okay. Dr. Diette, what I'm trying to</p> <p>3 get at here is, the underbelly, I guess, of your</p> <p>4 opinions seem to be from your report that cohort</p> <p>5 studies are inconsistent with the case-control</p> <p>6 studies, which they themselves are inconsistent</p> <p>7 because population-based studies and</p> <p>8 hospital-based studies, some were statistically</p> <p>9 significant and some were not. Correct?</p> <p>10 A Exactly, yes.</p> <p>11 Q Okay. And that's really the -- the guts</p> <p>12 of your report, correct?</p> <p>13 MS. BROWN: Objection to the form.</p> <p>14 THE WITNESS: I -- no. I mean, those</p> <p>15 are two very important points, but I'd say there's</p> <p>16 a heck of a lot more than that in the report.</p> <p>17 BY MS. PARFITT:</p> <p>18 Q Okay. Did you go through -- let's --</p> <p>19 let's talk a little bit about that.</p> <p>20 You described these relative risks of</p> <p>21 the case-control studies as small, weak -- small</p> <p>22 and weak, correct?</p> <p>23 A Correct.</p> <p>24 Q Okay. What type of -- those words</p> <p>25 "small and weak," are those scientific words?</p>
<p style="text-align: right;">Page 359</p> <p>1 particular heading, and so I've tried to get at</p> <p>2 this issue here too that if it were consistent</p> <p>3 that talc caused or was associated with ovarian</p> <p>4 cancer, I would expect to see it under a variety</p> <p>5 of circumstances, not just perineal dusting. And</p> <p>6 so one of the inconsistencies is that, you know,</p> <p>7 diaphragms and condoms, that we don't see that</p> <p>8 signal. So I'm just saying that that's an</p> <p>9 inconsistency. It's the opposite of consistency.</p> <p>10 And I guess too -- I mean just while</p> <p>11 we're even still on the -- on the types of</p> <p>12 studies, I mean the Taher study that, I guess, you</p> <p>13 know, even though it's not published yet, I mean</p> <p>14 they've got a summary risk for the hospital-based</p> <p>15 studies which is less than 1.0. Right. So now</p> <p>16 it's not even just like -- if -- I don't know</p> <p>17 whether we should like the Taher study or not, but</p> <p>18 it's out there, right. And so now we've got --</p> <p>19 Q It's out there. It's a piece of the</p> <p>20 evidence.</p> <p>21 A Yeah, it's something that's out there,</p> <p>22 so now we've got something that's unpublished from</p> <p>23 2018 that's got not even a positive risk. I mean,</p> <p>24 this -- this exercise of going to look and see</p> <p>25 what's over 1.0, there's a 0.94 or 6 or something</p>	<p style="text-align: right;">Page 361</p> <p>1 A So they're words that my colleagues and</p> <p>2 I use. I mean, it's a word that Dr. Rothman used</p> <p>3 when he did his analysis in 2000 and called the</p> <p>4 summary odds ratio or the risk -- risk of 1.3, he</p> <p>5 called it weak. I'm not sure whether he's citing</p> <p>6 a particular definition, but, you know, it --</p> <p>7 it's -- there's probably reasons, just like where</p> <p>8 you talk about a p-value of 0.05 not being the</p> <p>9 absolute line. I think it's why people have</p> <p>10 resisted trying to say that it has to be above an</p> <p>11 exact specific number.</p> <p>12 But I think we can all recognize risks</p> <p>13 that are large. You know, we know that a risk of</p> <p>14 10 is a large risk. We know that 20 is a large</p> <p>15 risk. We know that a relative risk of 1.01, it's</p> <p>16 got to be tiny, right, because it can't be any</p> <p>17 smaller than that on that particular scale.</p> <p>18 So somewhere in there we have to use</p> <p>19 some judgment, and I think if you got a 1.2 or</p> <p>20 1.3, I don't know who -- I don't know who thinks</p> <p>21 that's strong. It doesn't make any sense.</p> <p>22 Q Do you agree that having a weak</p> <p>23 association does not rule out a causal connection?</p> <p>24 MS. BROWN: Objection to the form.</p> <p>25 THE WITNESS: Wait a minute, say it</p>

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<p style="text-align: right;">Page 362</p> <p>1 again because I think --</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Having a weak association would not rule</p> <p>4 out a causal association.</p> <p>5 A That's correct.</p> <p>6 Q All right. Would you also agree that</p> <p>7 while the strength of an association is a</p> <p>8 guideline for drawing an inference of causation,</p> <p>9 there is no specified threshold required?</p> <p>10 MS. BROWN: Objection to the form.</p> <p>11 THE WITNESS: I don't think there's a</p> <p>12 specified threshold. I think it's a gradient,</p> <p>13 right, that you have to use as you're applying</p> <p>14 your judgment about all of the evidence. And that</p> <p>15 when you have a very small risk, you should be</p> <p>16 more concerned about the distorting effects of</p> <p>17 other factors, and if you have a larger risk, you</p> <p>18 can be less worried about those distorting</p> <p>19 factors.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q But you will agree with me under the</p> <p>22 Bradford Hill factors, strong association or weak</p> <p>23 association, neither are necessary for finding</p> <p>24 causality, correct?</p> <p>25 MS. BROWN: Objection to the form.</p>	<p style="text-align: right;">Page 364</p> <p>1 Q Secondhand smoke and lung cancer.</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: I think really the Surgeon</p> <p>4 General has put it at -- it's either about 1.7 or</p> <p>5 1.9, somewhere in there.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Okay. Let me show you -- I'm sorry.</p> <p>8 1.7 or 1.9.</p> <p>9 Let me show you a study by Kim. And</p> <p>10 it's entitled "Exposure to Secondhand Smoke and</p> <p>11 the Risk of Cancer in Never Smokers." And I'll</p> <p>12 represent that it's in the International Journal</p> <p>13 of Environment, 2018. And this would be a</p> <p>14 meta-analysis by Dr. Kim.</p> <p>15 A Do you know, is it something I cited or</p> <p>16 is this new -- new to me or --</p> <p>17 Q I did not see it in your --</p> <p>18 A Okay. Thank you.</p> <p>19 Q -- list of references.</p> <p>20 In fact, good question. None of the 167</p> <p>21 articles that were in your curriculum vitae did I</p> <p>22 see that you cited in support for your expert</p> <p>23 report; is that correct?</p> <p>24 A That would -- I'm sure that's correct.</p> <p>25 Q Okay. Okay. Do you see that?</p>
<p style="text-align: right;">Page 363</p> <p>1 THE WITNESS: So there isn't a single</p> <p>2 one of his considerations that all by itself is</p> <p>3 completely necessary, right. It's a -- it's a</p> <p>4 method to pull together a variety of, you know,</p> <p>5 information about the studies. But he -- he</p> <p>6 certainly does give us some guidance about what</p> <p>7 "strong" and "not strong" might mean and the</p> <p>8 implications of that.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q But we can agree sitting here today that</p> <p>11 those general terms, "weak," "small," do not</p> <p>12 dictate whether or not there is causality.</p> <p>13 MS. BROWN: Objection to the form.</p> <p>14 THE WITNESS: They don't dictate it.</p> <p>15 They inform it.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q You mentioned that the -- I want to come</p> <p>18 back to that one in a second.</p> <p>19 Now, you, yourself, have actually done</p> <p>20 secondhand smoke studies, correct?</p> <p>21 A I've done studies that include</p> <p>22 secondhand smoke as a measure.</p> <p>23 Q Okay. What is your understanding of the</p> <p>24 relative risks for secondhand smoke?</p> <p>25 A For what?</p>	<p style="text-align: right;">Page 365</p> <p>1 A I do, yes.</p> <p>2 Q Okay. And if you look in the abstract,</p> <p>3 do you see where the authors determined that the</p> <p>4 relative risks for passive smoke exposure and lung</p> <p>5 cancer in never users was a relative risk rather</p> <p>6 than of 1.2.</p> <p>7 Do you see that? Take a moment.</p> <p>8 A Yeah.</p> <p>9 Q We'll put it on the ELMO.</p> <p>10 A So we're looking at the abstract?</p> <p>11 Q We are, mm-hmm.</p> <p>12 A And saying -- so odds ratio involving</p> <p>13 never smokers with significant exposure to</p> <p>14 secondhand compared to never smokers was 1.163.</p> <p>15 Q Okay. Do you see where it says:</p> <p>16 "Passive smoke exposure and lung cancer in never</p> <p>17 users was a relative risk of 1.245"?</p> <p>18 And we can go ahead and circle that.</p> <p>19 A That's for females?</p> <p>20 Q Yes.</p> <p>21 A For females, yeah, 1.245.</p> <p>22 Q Okay. So we had a 1.245 for females,</p> <p>23 and, I'm sorry, you said a 1.16 for secondhand all</p> <p>24 comers, right?</p> <p>25 A Exactly right.</p>

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<p style="text-align: right;">Page 366</p> <p>1 Q Okay. Let me show you as well the Lv 2 study, and it was a 2015 study. "Risk of 3 All-Cause Mortality Associated With Secondhand 4 Smoke." 5 A Do I have that? 6 Q I'm getting that for you. Hold on one 7 second. 8 A Oh, I'm sorry. I thought I -- 9 Q No, no worries. 10 A I thought I missed it. 11 (Diette Exhibit No. 23 was marked 12 for identification.) 13 BY MS. PARFITT: 14 Q Do you have that in front of you? 15 A Yes. So this is by Lv? 16 Q That's right. 17 A The last name, yeah. 18 Q And now again, looking at the abstract 19 section, does it report the relative risk for 20 never smokers exposed to secondhand smoke versus 21 unexposed? 22 A So the pooled relative risk for never 23 smokers compared to those -- is that -- so that 24 first sentence of the results -- 25 Q That's right --</p>	<p style="text-align: right;">Page 368</p> <p>1 associations that are implementing those types of 2 programs to reduce secondhand smoke for fear of 3 lung cancer have accepted this type of data, 1.1, 4 1.2, for purposes of making those policy 5 decisions? 6 A So I don't know -- 7 MR. LOCKE: Objection. 8 THE WITNESS: Oops, sorry. 9 Like, I don't -- I don't know what 10 inputs they -- they used, and I don't -- I'm not 11 saying they wouldn't, but I don't know whether 12 they would use these risks to drive that or not. 13 BY MS. PARFITT: 14 Q Okay. You would agree with me, though, 15 that the risk of 1.1 and 1.2 are very -- are 16 actually less than the relative risks that we've 17 seen with talcum powder products and ovarian 18 cancer, correct? 19 MS. BROWN: Objection to the form. 20 THE WITNESS: So it's less than the 21 pooled odds ratio from the case-control studies in 22 the meta-analyses. 23 BY MS. PARFITT: 24 Q Okay. Now, you yourself have done 25 studies on indoor particulate matter, correct?</p>
<p style="text-align: right;">Page 367</p> <p>1 A -- 1.18? 2 Q Correct. And they then report in the 3 all-cause mortality and RR was 1.23 for 4 cardiovascular diseases. Do you see that? 5 A Yeah, although -- exactly right, yep. 6 Q Okay. Now, there have been -- and this 7 is work that you do as well, correct? 8 MS. BROWN: Objection to the form. 9 BY MS. PARFITT: 10 Q You do research work on secondhand 11 smoke? 12 A I have done, yeah, and still do. 13 Q Okay. And are you aware that in the 14 United States and in other countries, there have 15 been health programs implemented to reduce 16 secondhand smoke based upon relative risks, like 17 you've just seen, 1.1, 0.8, 1.2? 18 MR. LOCKE: Objection. 19 THE WITNESS: I mean, I don't know if 20 the programs were based on these studies, and 21 there certainly have been higher relative risks 22 before. But I -- but I agree that there are 23 programs to reduce secondhand smoke exposure. 24 BY MS. PARFITT: 25 Q Okay. And would you agree today that</p>	<p style="text-align: right;">Page 369</p> <p>1 A Correct. 2 Q Okay. In particular, you published a 3 study with McCormack and Diette on common 4 household exposures? 5 A I've published a bunch with her, so I 6 don't know which -- which particular one that is. 7 Q All right. It's Common -- it's Common 8 Household Products, 2008." McCormack is the lead 9 article -- author. 10 A What journal? 11 Q It is in the Environmental Res, 12 Environmental -- 13 A Environmental research. 14 Q -- Research. And it's dated February 15 2008. And take a minute to -- 16 (Diette Exhibit No. 24 was marked 17 for identification.) 18 BY MS. PARFITT: 19 Q Do you have that in front of you? 20 A I do. 21 Q Okay. Now, if you look at the first 22 page under the abstract, about the third line 23 down -- excuse me, fourth line down, it says: 24 "There is a public health imperative to 25 characterize indoor source as being less</p>

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<p style="text-align: right;">Page 370</p> <p>1 extensively characterized" -- excuse me. I'm</p> <p>2 sorry.</p> <p>3 "There is a public health imperative to</p> <p>4 characterize indoor sources of PM" -- I assume</p> <p>5 that's particulate matter?</p> <p>6 A Correct.</p> <p>7 Q -- "with this vulnerable population to</p> <p>8 enable effective intervention strategies."</p> <p>9 Did I read that correctly?</p> <p>10 A You did.</p> <p>11 Q Okay. You were the lead -- one of the</p> <p>12 lead authors in that study?</p> <p>13 A Yeah, I was, by position, the senior</p> <p>14 author, but I was the head of the -- the study</p> <p>15 that produced this paper.</p> <p>16 Q All right. And what is -- and do you</p> <p>17 have an opinion with regard to what the relative</p> <p>18 risks are for indoor ambient particulate matter?</p> <p>19 A For what?</p> <p>20 Q For --</p> <p>21 A You mean qualitative, like what</p> <p>22 illnesses they cause or --</p> <p>23 Q Yes, with regard -- I believe you</p> <p>24 studied a bit of asthma, so I believe it would be</p> <p>25 the relative risk of indoor particulates and</p>	<p style="text-align: right;">Page 372</p> <p>1 MS. BROWN: Objection to the form. You</p> <p>2 need the disease to link the --</p> <p>3 MS. PARFITT: Lung. Lung.</p> <p>4 MS. BROWN: You mean cancer? Objection</p> <p>5 to the form.</p> <p>6 THE WITNESS: Anyway, I can't answer it.</p> <p>7 You need more in the sentence or the question in</p> <p>8 order for me to be able to answer it.</p> <p>9 BY MS. PARFITT:</p> <p>10 Q Okay. Are there any -- fair enough.</p> <p>11 Are there any reported relative risks</p> <p>12 between indoor particulate matter and lung</p> <p>13 disease?</p> <p>14 MS. BROWN: Objection to the form.</p> <p>15 THE WITNESS: I'd want to be super</p> <p>16 careful about what we're saying is lung disease,</p> <p>17 because some people might think that that means</p> <p>18 the risk of developing a particular lung disease,</p> <p>19 and others might mean the worsening of an existing</p> <p>20 disease or a lung function abnormality.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q Okay. Do you know what the relative</p> <p>23 risk is between indoor particulate matter and</p> <p>24 asthma?</p> <p>25 A The risk of developing asthma?</p>
<p style="text-align: right;">Page 371</p> <p>1 asthma?</p> <p>2 A Well, there's not one single way to</p> <p>3 answer that, right. So this -- this paper doesn't</p> <p>4 look like the one that's actually quantified it,</p> <p>5 right. We have other ones that look at the</p> <p>6 increase in, say, symptoms, for example, or</p> <p>7 exacerbations per very small increment in</p> <p>8 particulate matter.</p> <p>9 So like, I think if you -- if you're</p> <p>10 looking at our studies, you're not going to find a</p> <p>11 relative risk that's, like -- that's analogous to</p> <p>12 these where this is the relative risk of an</p> <p>13 outcome for secondhand smoke, yes/no. Ours are</p> <p>14 reported not by that but by little tiny increments</p> <p>15 or decrements of -- of particle concentrations.</p> <p>16 Q Do you know what the relative risk is</p> <p>17 for indoor ambient air?</p> <p>18 A That's --</p> <p>19 MS. BROWN: Objection to the form.</p> <p>20 THE WITNESS: That's not a full</p> <p>21 question.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Do you -- is there a relative risk for</p> <p>24 exposure to the lungs in indoor particulate</p> <p>25 matter?</p>	<p style="text-align: right;">Page 373</p> <p>1 Q Correct.</p> <p>2 A It's not --</p> <p>3 MS. BROWN: Objection to the form.</p> <p>4 THE WITNESS: Sorry. It's not known.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q It's not known.</p> <p>7 A Not known.</p> <p>8 Q It's not been published.</p> <p>9 A Well, I can't say there's not a single</p> <p>10 paper out there, but at this point the -- a</p> <p>11 summary of the evidence is that we can't say for</p> <p>12 sure that it's -- that it causes asthma.</p> <p>13 Q Have you reviewed in any of the</p> <p>14 literature published data with regard to airborne</p> <p>15 particles -- indoor airborne particles and asthma</p> <p>16 as to what the relative risk may be?</p> <p>17 MS. BROWN: Objection to form.</p> <p>18 THE WITNESS: Relative risk of?</p> <p>19 BY MS. PARFITT:</p> <p>20 Q Relative risk of asthma from exposure to</p> <p>21 indoor air particulate.</p> <p>22 MS. BROWN: Objection to the form.</p> <p>23 THE WITNESS: So I -- I've read a ton of</p> <p>24 stuff about it. I mean if you've got a particular</p> <p>25 article, I'm happy to read it and interpret it.</p>

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<p>1 But as of this point, I think we -- should I 2 explain or just -- 3 BY MS. PARFITT: 4 Q No, I -- all I really want to know in 5 the interest of time is whether or not you have 6 reviewed any of the scientific literature data 7 that reports what the relative risk is for indoor 8 particulate matter and the risk of getting asthma? 9 MS. BROWN: Objection to the form. 10 BY MS. PARFITT: 11 Q And if you haven't, that's fine. 12 A Oh, my gosh, no, it's not that. I have. 13 I just don't think that you can answer that 14 question. I'm not saying there's not some study 15 out there that may estimate a risk for that, but 16 it isn't established. Like, at this point, we 17 cannot say in 2019 that indoor particulate matter 18 causes asthma. 19 And -- and you have to say more to the 20 sentence. So let's just talk about like adults 21 living in the city. We can't say that. You 22 know -- you know, there's -- there's studies that 23 have looked at the relative risk of indoor 24 cooking, which is predominantly particulate 25 matter, in developing countries, but even the</p>	<p>1 meter cubed. It may be from a particular source, 2 like traffic-related pollution or not. 3 I mean there's more to it. There's not 4 just like some summary that -- that I can -- I can 5 make. Maybe you can find somebody that can just 6 say particulate matter has this risk of causing 7 asthma. I haven't seen it. 8 But it's not there aren't like a whole 9 bunch of studies looking at the relationship 10 between indoor and outdoor particulate matter and 11 lung disease as both, you know, developing newly 12 and worsening the existing ones. 13 BY MS. PARFITT: 14 Q Right. Does secondhand smoke cause lung 15 cancer? 16 MS. BROWN: Objection to the form. 17 THE WITNESS: It seems -- it seems that 18 that -- that has been established. 19 (Counsel conferring.) 20 BY MS. PARFITT: 21 Q Okay. Let's talk a little bit -- 22 THE WITNESS: We're just doing a time 23 check. I'm just trying -- do you know roughly how 24 much we -- 25 THE VIDEOGRAPHER: Five hours, 34</p>
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<p>1 asthma evidence is not fully developed. 2 So it's just -- it's one of those things 3 where you may find a paper that has an estimate, 4 but it hasn't been fully established yet. 5 Q All right. Do you -- I understand it's 6 not fully established, but are there reported 7 relative risks from the scientific literature? 8 MS. BROWN: Objection. 9 THE WITNESS: I'm sure there are. 10 MS. BROWN: Objection -- 11 THE WITNESS: I'm sure there are, but -- 12 BY MS. PARFITT: 13 Q There are. Do you know what they are? 14 MS. BROWN: Objection to the form. 15 THE WITNESS: Oh, my gosh. 16 BY MS. PARFITT: 17 Q If you know. If -- like, do you know 18 there is a range of relative risks between 19 exposure to indoor particulate matter and asthma? 20 MS. BROWN: Objection to the form of the 21 question. 22 THE WITNESS: I've got to see what 23 you're talking about, because I think that when 24 you ask it that way, there may be some estimate 25 based on a particular number of micrograms per</p>	<p>1 minutes. 2 THE WITNESS: So a little under an hour 3 and a half? Did you guys want to do a -- 4 MS. PARFITT: A quick break here? Sure. 5 THE WITNESS: -- or a break here or 6 wait? 7 MS. PARFITT: No, that's fine. We can 8 take a quick one now. That's fine. 9 THE VIDEOGRAPHER: The time is 3:50 p.m. 10 We're going off the record. 11 (Recess.) 12 THE VIDEOGRAPHER: The time is 4:10 p.m. 13 We're back on the record. 14 We're on the record, by the way. 15 (A discussion was held off the record.) 16 (Diette Exhibit Nos. 25 and 26 17 were marked for identification.) 18 BY MS. PARFITT: 19 Q Are you ready, Dr. Diette? 20 A I am. Thank you. 21 Q Very good. 22 THE VIDEOGRAPHER: Microphone, Counsel. 23 BY MS. PARFITT: 24 Q Dr. Diette, I -- I asked you a little 25 bit earlier about the relative risk for secondhand</p>

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<p style="text-align: right;">Page 378</p> <p>1 smoke and -- and lung cancer. 2 And what I would like you to do is -- 3 and I apologize, I don't have copies of this -- so 4 I'm showing you what is the report of the Surgeon 5 General, I believe it was back in 2006, "The 6 Health Consequences of Involuntary Exposure to 7 Tobacco Smoke, A Report of the Surgeon General." 8 Have you read that in the past? 9 A So definitely not every word, but I've 10 read big chunks of it. 11 Q Okay. I figured with your work you may 12 have. 13 A Yeah. 14 Q All right. Let me direct your attention 15 to -- 16 MS. PARFITT: And I apologize to all, so 17 you have to look on the camera -- on the screen. 18 MS. BROWN: Okay. So just for the 19 record, we don't have copies of this, and so I 20 will object to the fact that we have no context or 21 ability to look at the document ourselves. 22 MS. PARFITT: All right. 23 BY MS. PARFITT: 24 Q And again, Doctor, you've reviewed this 25 report, correct, in the past?</p>	<p style="text-align: right;">Page 380</p> <p>1 Q That's all right. 2 -- is related to secondhand smoke and 3 lung cancer? 4 MS. BROWN: Objection to the form. 5 THE WITNESS: It looks like it there. I 6 remember there's other numbers in there as well, 7 but I mean, I remember it being 1-point something 8 and -- 9 BY MS. PARFITT: 10 Q Does that refresh my memory? 11 MS. BROWN: Well, let him finish, 12 please. 13 THE WITNESS: I think there's somewhere 14 else in there where there's other estimates, but 15 still not like -- not sky high. Still less than 16 2.0. 17 BY MS. PARFITT: 18 Q But you don't disagree with the Surgeon 19 General's conclusion that the pooled evidence 20 indicates a 20 to 30 percent increase in the risk 21 of lung cancer from secondhand smoke exposure 22 associated with living with a smoker, correct? 23 MR. LOCKE: Objection. 24 MS. BROWN: Objection. He doesn't have 25 the document, he can't review it.</p>
<p style="text-align: right;">Page 379</p> <p>1 A In the past, and I've read parts of it, 2 but as you know, I mean it's a humongous -- 3 Q It is big. 4 A -- document, and so some parts 5 weren't -- weren't for me. 6 Q All right. I want to focus your 7 attention on the conclusions of the Surgeon 8 General's report. 9 And 1: "The evidence is sufficient to 10 infer a causal relationship between secondhand 11 smoke exposure and lung cancer among lifetime 12 nonsmokers. This conclusion extends to all 13 secondhand smoke exposure, regardless of location. 14 "2. The pooled evidence that indicates" 15 -- sorry -- "the pooled evidence indicates a 20 to 16 30 percent" -- that would be a 1.2 or 1.3 relative 17 risk -- "increase in the risk of lung cancer from 18 secondhand smoke exposure associated with a 19 smoker." 20 Did I read that correctly? 21 A You did. 22 Q And is that what the -- are those the 23 numbers, 1.2 and 1.3, the relative risks that the 24 Surgeon General has concluded is -- 25 A Um -- I'm sorry.</p>	<p style="text-align: right;">Page 381</p> <p>1 BY MS. PARFITT: 2 Q Are you disputing that conclusion? 3 MS. BROWN: Objection. He has no basis 4 to do it, he doesn't have the document. 5 BY MS. PARFITT: 6 Q Are you disputing that, Doctor? 7 A I would -- 8 MR. LOCKE: Objection. 9 THE WITNESS: I would say it fits with 10 what I understood to be true at the time that that 11 was published. 12 BY MS. PARFITT: 13 Q Fair enough. Thank you. I appreciate 14 that. 15 Dr. Diette, is it fair that -- to say 16 that we don't have, and you've not reviewed, any 17 Johnson -- Johnson & Johnson specific epidemiology 18 with regard to a study of just Johnson & Johnson 19 Baby Powder? 20 MS. BROWN: Objection to the form. 21 THE WITNESS: That is correct. 22 BY MS. PARFITT: 23 Q Okay. And so what we rely on, and what 24 you've relied on, rather, is data and 25 epidemiological science on all comers, all brands,</p>

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<p style="text-align: right;">Page 382</p> <p>1 correct?</p> <p>2 MS. BROWN: Objection to the form.</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: I -- I wouldn't</p> <p>5 characterize it exactly that way. I mean I would</p> <p>6 say that I can't really sort between different</p> <p>7 brands based on the epidemiologic literature, but</p> <p>8 whatever all brands is, I don't -- you know, I</p> <p>9 don't know what that represents.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q And would it be fair then if one product</p> <p>12 that contained -- one product, talcum powder</p> <p>13 product contained asbestos, and another did not,</p> <p>14 that would result in a conclusion that would draw</p> <p>15 it towards the null? Is that fair?</p> <p>16 MS. BROWN: Objection to the question.</p> <p>17 THE WITNESS: I don't understand that.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q Okay.</p> <p>20 A I mean I understand the idea of drawing</p> <p>21 something to the null. I just don't understand --</p> <p>22 Q Sure.</p> <p>23 A -- what preceded that.</p> <p>24 Q If you have a product like Johnson &</p> <p>25 Johnson, and you -- and it has a carcinogen in it,</p>	<p style="text-align: right;">Page 384</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Okay. When you say it doesn't change</p> <p>3 the totality of the evidence that we have</p> <p>4 available for us, isn't it true that the presence</p> <p>5 of a carcinogen, like asbestos in talcum powder</p> <p>6 products, supports the biological -- biologically</p> <p>7 plausible mechanism for association between talcum</p> <p>8 powder products and ovarian cancer?</p> <p>9 MS. BROWN: Objection to the form of the</p> <p>10 question.</p> <p>11 THE WITNESS: I -- I'd say no. And for</p> <p>12 reasons, if you want them, or just leave it at no.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q Well, you've testified that asbestos is</p> <p>15 a carcinogen. Correct?</p> <p>16 A Correct.</p> <p>17 Q All right. And the fact that asbestos</p> <p>18 might be in the talcum powder product does not</p> <p>19 impact your opinions with regard to the increased</p> <p>20 biologically plausible mechanism for talc to cause</p> <p>21 ovarian cancer.</p> <p>22 MS. BROWN: Objection to the form. Are</p> <p>23 you talking about a Johnson & Johnson product?</p> <p>24 MS. PARFITT: Just generally.</p> <p>25 MS. BROWN: Objection to the form.</p>
<p style="text-align: right;">Page 383</p> <p>1 and you lump it together with other products that</p> <p>2 are not infected or contaminated with asbestos,</p> <p>3 what does that do to the overall relative risk --</p> <p>4 A Oh.</p> <p>5 Q -- when studying that product?</p> <p>6 MS. BROWN: Objection to the incomplete</p> <p>7 hypothetical.</p> <p>8 THE WITNESS: So concept and reality,</p> <p>9 right. So the concept would be, if you knew that</p> <p>10 there were enough asbestos that led to an exposure</p> <p>11 that was enough in order to cause a disease from</p> <p>12 one product, and it was pooled with another</p> <p>13 product that didn't have that same amount or</p> <p>14 didn't have any asbestos but you knew that there</p> <p>15 was enough to cause disease, then it would -- it</p> <p>16 would do exactly what you're saying, is it would</p> <p>17 move it towards -- towards one.</p> <p>18 The reality is there wouldn't be any</p> <p>19 impact whatsoever because the epidemiology already</p> <p>20 takes into account whatever those brands are, and</p> <p>21 so it doesn't change the totality of the evidence</p> <p>22 that we have available for us.</p> <p>23 So concept, I mean you could sort of</p> <p>24 imagine what you're saying to be true, but</p> <p>25 reality, no.</p>	<p style="text-align: right;">Page 385</p> <p>1 THE WITNESS: It -- it does not.</p> <p>2 As you ask these things, I'm trying to</p> <p>3 figure out if I'm supposed to explain what I'm</p> <p>4 saying or is --</p> <p>5 MS. BROWN: No, you answered the</p> <p>6 question.</p> <p>7 THE WITNESS: Okay.</p> <p>8 MS. BROWN: She'll ask you another one</p> <p>9 if she has one.</p> <p>10 THE WITNESS: Okay. All right.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Does Johnson & Johnson sell baby powder</p> <p>13 that's 99 percent asbestos and 1 percent</p> <p>14 fragrance?</p> <p>15 MS. BROWN: Objection to the form of the</p> <p>16 question.</p> <p>17 THE WITNESS: If they do, I'm not aware</p> <p>18 of that.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q Okay. And if I understand, the presence</p> <p>21 of asbestos in a talcum powder product does not in</p> <p>22 your mind impact the biologically plausible</p> <p>23 mechanism for talcum powder products to cause</p> <p>24 ovarian cancer.</p> <p>25 MR. LOCKE: Objection.</p>

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<p style="text-align: right;">Page 386</p> <p>1 THE WITNESS: No, there's not enough 2 information in what you said there. 3 BY MS. PARFITT: 4 Q What would you need? 5 A So I would need a couple of things. One 6 is I would need to have some estimate of what the 7 dose would be, and some assurance from somewhere, 8 which I don't have, that that represented a dose 9 that was sufficient to cause -- and by dose, I'm 10 talking about dose of asbestos, right -- that that 11 was a sufficient dose to cause ovarian cancer. 12 And based on what I've seen, I can't 13 make that link. I can't -- I haven't seen 14 anything that says that there's a plausible 15 concentration or dose that people would be exposed 16 to that links to anything I can find in the 17 epidemiologic literature about how much, if any, 18 it would take in order to -- to cause ovarian 19 cancer. And what I -- should I finish? 20 Q Mm-hmm, yeah, finish. 21 A Okay. I'm sorry. 22 Q I'm trying not to interpret you. 23 A No, no, you're not. I didn't mean -- I 24 didn't think you were. 25 Q So doing better.</p>	<p style="text-align: right;">Page 388</p> <p>1 And then I think if you -- if you pair 2 that with more modern studies, if you take like 3 the Reid study from Australia, you take women who 4 worked, you know, in and around a crocidolite 5 mine, they certainly had enough exposure to get 6 asbestos-related diseases, but they don't get 7 ovarian cancer. 8 And so I think that the -- you know, the 9 sum total of all that just -- it doesn't make 10 sense that just knowing the fact that there's some 11 particle -- even if it's true, that some particle 12 of asbestos is going to be enough to cause 13 disease. 14 Q Okay. Have you -- have you read -- I 15 didn't see it in your reliance list -- Reid, 2012? 16 A I have two Reeds, I think, and if I only 17 listed one, I meant to include two. 18 Q Yeah, you only listed 2011 Reid. You 19 didn't list 2012 Reid. 20 A I meant -- so I don't know which one is 21 there. There's one from Whitnum, which is the 22 study of the women that -- you know, that I was 23 just describing, and a separate one is -- it's 24 basic -- basically like a meta-analysis or a 25 reanalysis of the ovarian cancer and asbestos</p>
<p style="text-align: right;">Page 387</p> <p>1 A I didn't think you were. 2 So I mean there's more, right. I mean 3 so the -- if you look at IARC and what those 4 studies represented, they represent for the most 5 part -- and by IARC, I'm talking about IARC and 6 ovarian cancer and asbestos -- you know, mostly 7 circumstances that aren't typical of American 8 women. For example, so women in Europe who were 9 working at a time and place when there was 10 different forms and lots of asbestos that may have 11 been sufficient to cause other asbestos-related 12 diseases. 13 So if you -- if those -- if those 14 findings are absolutely accurate -- you know, you 15 take away the issue of misclassification or 16 anything else -- if they're absolutely accurate, 17 you've got a relative risk in the neighborhood of 18 like 1.75 or something like that. 19 So I'm not saying that's not an 20 important risk, but it's not a huge risk, right? 21 So we're taking heavy industrial exposure to get 22 to a 1.75. I haven't seen anything that could 23 tell me that anything we're talking about here 24 could possibly rise to the level of heavy 25 industrial exposure.</p>	<p style="text-align: right;">Page 389</p> <p>1 literature. 2 Q Okay. Do you recall from your reading 3 that the scientists in Reid 2012 determined that 4 childhood exposure to asbestos was associated with 5 an increased risk of cancer mortality which was 6 3.5 times greater than the general population? Do 7 you recall those numbers? 8 A I don't, but cancer mortality to -- 9 MS. BROWN: Objection. 10 THE WITNESS: Can you tell me which -- 11 because I don't remember which year links to which 12 Reid study. 13 BY MS. PARFITT: 14 Q That was the 2012 that I was speaking 15 of. 16 A No, I understand that. I heard the 17 year, but I don't know what the title is. 18 Q Oh, the title is "All-cause mortality in 19 cancer incidence among adults exposed to blue 20 asbestos during childhood." 21 A I think that's a third study then, 22 because I think the two I'm referring to are -- 23 are two different ones. 24 Q All right. So did you read the 2012 or 25 that just wasn't one you read?</p>

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<p>1 MS. BROWN: Well, Counsel, can you show 2 it to him and he'll tell you? 3 MS. PARFITT: Sure. 4 THE WITNESS: I don't know if either of 5 the ones that I cite, you know, that I'm familiar 6 with are from 2012, but I don't think I read the 7 one that you're talking about. 8 BY MS. PARFITT: 9 Q Okay. From looking at your curriculum 10 vitae and the studies you cited, you cited Reid -- 11 actually you cited three Reids. You cited Reid 12 2011, you cited Reid 2008, and you cited Reid 13 2009. The study that you did not cite was Reid 14 2012. 15 A That -- that sounds believable. That 16 makes sense. 17 Q All right. So for purposes of the 18 opinions in your report, you did not rely on Reid 19 2012, is that fair? 20 MS. BROWN: Objection to the form of the 21 question. 22 THE WITNESS: I -- I don't think I'm 23 familiar with that study. 24 BY MS. PARFITT: 25 Q Okay. Fair enough.</p>	<p>1 THE WITNESS: I'm not disagreeing with 2 you, I think that's the language they use, but 3 they -- they used their -- their strongest -- 4 their strongest grading. 5 BY MS. PARFITT: 6 Q How many of the IARC studies that formed 7 the basis for IARC's conclusion that asbestos 8 causes ovarian cancer was there information 9 concerning the exposure and the dose? 10 A So I think you said something that you 11 didn't mean to, because I think you said how many 12 of the IARC studies that IARC considered. I 13 think -- did you mean how many of the underlying 14 studies that IARC considered? 15 Q Correct. 16 A Okay. And so there's at least five that 17 I remember that were like sort of factory worker 18 type studies, and then I think there were a couple 19 of more. I'd have to go back, though, to look and 20 see what -- what they had about dose, if anything. 21 My -- I'm thinking like at least for the World 22 War II era ones, they probably didn't have good 23 measures at all, you know, if any. 24 Q Okay. Let me show you what I will have 25 marked as Exhibit 27.</p>
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<p>1 Are you able to share with us, 2 Dr. Diette, what the minimum dose of asbestos is 3 necessary in order to cause an ovarian cancer? 4 MS. BROWN: Objection to the form of the 5 question. 6 THE WITNESS: I haven't seen that 7 published. I can tell you that at least in one of 8 those Whitnum studies that women were exposed to 9 as much as 40 fiber/cc years cumulatively of 10 crocidolite, and -- and that apparently wasn't 11 enough to cause ovarian cancer. But I didn't see, 12 you know, good measurements or estimates from 13 the -- the more historic to say what the exposures 14 were. 15 BY MS. PARFITT: 16 Q Okay. IARC looked at the issue of 17 asbestos and ovarian cancer, correct? 18 A They did. 19 MS. BROWN: Form. 20 THE WITNESS: Sorry. 21 BY MS. PARFITT: 22 Q All right. IARC concluded that asbestos 23 causes ovarian cancer. 24 MS. BROWN: Form. 25 MR. LOCKE: Objection.</p>	<p>1 (Diette Exhibit No. 27 was marked 2 for identification.) 3 MR. ROSEN: 26, for the record, is the 4 Surgeon General's report, which we'll supplement 5 with a paper copy. 6 THE WITNESS: The same one -- the same 7 one that we were talking about before the 8 secondhand smoke or involuntary smoke? 9 MR. ROSEN: Right, so there won't be a 10 26 in the file. 11 THE WITNESS: Got you. 12 BY MS. PARFITT: 13 Q Let me show you what we have marked as 14 Exhibit 27. 15 Do you have that in front of you? 16 A I have the "Arsenic, Metals, Fibres and 17 Dusts," 100C IARC. 18 Q That's correct, that's the right one. 19 Okay. Let me direct your attention to 20 the bottom of page 253. 21 Do you have that? 22 A 253? 23 Q 253, correct. 24 A I do. 25 Q All right. And it says: "An</p>

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<p>1 examination of the association between asbestos 2 and ovarian cancer was not undertaken by the IOM," 3 and then it has a 2000 -- a 2006 date. Correct? 4 A Yes. 5 Q Okay. Now, before we get to Table 2.8, 6 what I want you to do is turn over to page 256. 7 All right. And again, directing your 8 attention to the far right column. Are you there? 9 And it starts with, "Working group"? 10 A I am. I'm sorry, I'm distracted because 11 I think there's -- 12 MS. BROWN: It has a weird -- 13 THE WITNESS: -- there's like a font 14 issue or something, like somebody's printer didn't 15 have the right -- 16 BY MS. PARFITT: 17 Q That might have been ours. I apologize. 18 Not ideal circumstances. 19 All right. Do you see where it says, 20 "The working group"? 21 A I do. 22 Q All right. "The working group noted 23 that a causal association between exposure to 24 asbestos and cancer of the ovary was clearly 25 established based on five strongly positive cohort</p>	<p>1 Q Okay. Do you see where the working 2 group of IARC considered all of the data, and they 3 made a determination that there were not, at the 4 bottom, sufficient -- they ruled out the 5 possibility that there may have been a 6 misdiagnosis. 7 Do you see that? 8 MS. BROWN: Objection to the form. 9 THE WITNESS: I see that they've -- that 10 they reached that -- that conclusion. 11 BY MS. PARFITT: 12 Q Okay. And that's different than the 13 conclusion you raised in your report, correct? 14 A Well, it's different -- 15 MS. BROWN: Objection. 16 THE WITNESS: It is different, yes. 17 BY MS. PARFITT: 18 Q All okay. Right. Let's go back to 19 again page 253. 20 And you will see it references a table, 21 Table 2.8. Do you see that on the top of 254? 22 A Okay. 23 Q Okay. Got that. 24 Okay. Let me show you what we'll have 25 marked as Exhibit 28.</p>
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<p>1 mortality studies of women with heavy occupational 2 exposure to asbestos." 3 Do you see that? 4 A I do. 5 Q Okay. And then if you go -- and then it 6 cites those studies. 7 Do you see that? 8 A I do. 9 Q And go down to where it starts: "The 10 working group carefully considered the 11 possibilities that cases of peritoneal 12 mesothelioma may have been misdiagnosed as ovarian 13 cancer, and that these contributed to the observed 14 excesses." 15 Do you see that? 16 A I do. 17 Q Okay. Did I read that correctly? 18 A Yes. 19 Q Okay. In your report you stated that it 20 was your belief that perhaps the results were 21 limited by virtue of the fact that there may have 22 been misdiagnosis between peritoneal mesothelioma 23 and ovarian cancer cases. 24 Do you remember writing that? 25 A I do.</p>	<p>1 (Diette Exhibit No. 28 was marked 2 for identification.) 3 BY MS. PARFITT: 4 Q Okay. Diette Exhibit 28, if you will. 5 There you go. 6 MS. PARFITT: And, Counsel, I have a 7 copy for you. 8 MS. BROWN: Thank you. 9 MS. PARFITT: Of course. 10 Sorry, guys. I'm going to need one. 11 I'm sorry. I'll give you this one later. 12 BY MS. PARFITT: 13 Q Okay. I will represent to you that that 14 is -- that is Table 2.8, which is referenced in 15 the IARC report on page 253 and 254. 16 And it says: "Epidemiological studies 17 of asbestos exposure and ovarian cancer," and then 18 in parens, "and for comparison, lung cancer and 19 mesothelioma." 20 Do you see that? 21 A I do. 22 Q All right. Look over at the first study 23 mentioned there, the Atkinson study from 1982. 24 A Mm-hmm. 25 Q All right. Do you see that the relative</p>

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<p style="text-align: right;">Page 398</p> <p>1 risk for ovarian cancer and lung cancer, for 2 ovarian cancer it was 2.75, and for lung cancer it 3 was 2.41. Do you see that? 4 A I do. 5 Q Okay. Then move down to the Wignall and 6 Fox study. It's a 1982 study. Do you see that? 7 A I don't -- oh, yeah, the next one down, 8 yeah. 9 Q Okay, yeah. Do you see that the 10 relative risk for ovarian cancer were 2.13, and 11 for lung cancer 2.73? 12 A Correct. 13 Q And let's move down to Pira in 2005. Do 14 you see where the relative risk for ovarian cancer 15 were 2.61 and for lung cancer 2.82? 16 A I do. 17 Q All right. And then let's move to 18 Magnani, a 2008 study. 19 All right. Do you see -- and this is 20 one of the studies that the working group of IARC 21 looked at. They determined that the relative risk 22 for -- not determined -- they indicated that the 23 relative risk for ovarian cancer on the Magnani 24 study was 2.27, and for lung cancer 2.20. 25 Do you see that?</p>	<p style="text-align: right;">Page 400</p> <p>1 BY MS. PARFITT: 2 Q Sure. 3 A In one of your questions a little while 4 back, you were asking me to agree that you were 5 reading fine, and you were for the relative risks. 6 Q Yeah. 7 A None of these are relative risks, 8 though. They're SMRs and SIRs. So just a 9 slightly different -- 10 Q I appreciate that. Thank you. Thank 11 you for the correction. Thank you. 12 Next question. Do you intend to give an 13 opinion that fibrous talc is a carcinogen? 14 MS. BROWN: Form. 15 THE WITNESS: I'm not sure I understand 16 what fibrous talc is. 17 BY MS. PARFITT: 18 Q Okay. Let me direct your attention 19 to -- we'll go back to the IARC on ovarian 20 cancer -- or, excuse me, IARC on asbestos. 21 Paragraph 1.1 on page 219. 22 Are you there? 23 A Paragraph 1, yes. 24 Q Yes. Okay. Do you see where after it 25 has IARC, '73, and USGS, 2001, it states: "The</p>
<p style="text-align: right;">Page 399</p> <p>1 A I do. 2 Q All right. And let's go on to the 3 Ferrante study. Do you see that? 4 MS. BROWN: Where -- where are you? 5 MS. PARFITT: On the last page. 6 BY MS. PARFITT: 7 Q Do you see that? It's on the last page, 8 Ferrante, 2007. Do you see that? 9 A I do. 10 Q Okay. And the relative risk for ovarian 11 cancer was 1.43, and for lung cancer it was 1.17. 12 Now, I'll represent to you, Doctor -- 13 or, Dr. Diette, is it fair to say that this 14 Table 2.8 of epidemiological exposures, asbestos 15 exposure and ovarian cancer formed part of the 16 bases for IARC's decision in their IARC report 17 that asbestos -- or ovarian -- asbestos causes 18 ovarian cancer? 19 A I assume so, yeah. 20 Q Okay. All right. Let's talk a little 21 bit -- do you intend to give an opinion in this 22 case that fibrous talc is a carcinogen? 23 MS. BROWN: Objection to the form. 24 THE WITNESS: I just want to correct 25 something real quick.</p>	<p style="text-align: right;">Page 401</p> <p>1 conclusions reached in this monograph about 2 asbestos and its carcinogenic risks apply to these 3 six types of fibres wherever they are found, and 4 that includes talc containing asbestiform fibres." 5 Do you see that? 6 A Yes. 7 Q All right. Do you intend to give an 8 opinion in this case that talc containing 9 asbestiform fibers can cause ovarian cancer? 10 MS. BROWN: Objection to the form. 11 That's different than the original question. 12 MS. PARFITT: It is. 13 MS. BROWN: Did you mean it to be? 14 MS. PARFITT: No. I mean the new 15 question. 16 MS. BROWN: Okay. 17 THE WITNESS: So, because to me, the way 18 I have read this before and then also again now, I 19 think, although I can't know what they were 20 intending, but this to me says basically talc with 21 asbestos in it -- what we would agree is talc with 22 asbestos in it, as opposed to something else. 23 And I don't think you need the "talc 24 containing." I think you could say anything 25 containing asbestos, you know, could potentially</p>

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<p style="text-align: right;">Page 402</p> <p>1 increase carcinogenic risk if there's enough of a 2 dose. 3 BY MS. PARFITT: 4 Q Okay. Did you see anywhere in the IARC 5 working group document that we've been talking 6 about that the working group determined that there 7 was a causal association between asbestos and 8 ovarian cancer, but it depended on the dose? 9 MR. LOCKE: Objection. 10 MS. BROWN: Objection to the form of the 11 question. 12 THE WITNESS: I don't recall. 13 BY MS. PARFITT: 14 Q Okay. You've worked an secondhand smoke 15 studies, correct? 16 A Yes. 17 Q How do you determine the dose for those? 18 MS. BROWN: Objection to the form. 19 THE WITNESS: So the dose of secondhand 20 smoke? 21 BY MS. PARFITT: 22 Q Mm-hmm. 23 A So it depends, right. So at the moment, 24 it -- so it depends upon which kind of study. And 25 when you say "you," do you mean you in the broad</p>	<p style="text-align: right;">Page 404</p> <p>1 sufficient dose. It's not a measurement of dose. 2 It's an indicator of sufficient -- sufficient 3 exposure to be linkable to things like lung 4 cancer. 5 The same kind of question for being 6 around coworkers, and so a yes/no to that has been 7 sufficient. 8 In our other studies, we -- we get more 9 precise so that we'll -- and use a variety of 10 overlapping methods. So one is to -- to query -- 11 if it's a child study, to query the parent about 12 the number of cigarettes that are smoked per day 13 in the home, and with a very elaborate procedure 14 of asking not only the person who is answering the 15 questionnaire but about all the other people that 16 are in and out of the house that day, so we get a 17 count of cigarettes. 18 We also use different types of 19 particulate matter monitors, and we've established 20 that you can estimate about 1 microgram per meter 21 cubed of particulate matter per cigarette smoked 22 in the home. So we've got an estimate that way. 23 We -- we collect nicotine and cotinine 24 from a variety of sources, so we've collected 25 hair, saliva, urine, and blood. And so depending</p>
<p style="text-align: right;">Page 403</p> <p>1 sense or me, Greg Diette? 2 Q Well, Greg Diette has been doing 3 research on secondhand smoke, and you, Greg 4 Diette, has indicated that dose is important to 5 you. So what I'd like to know is how you measure 6 the dose in your secondhand smoke. 7 A Yeah, so a lot of different -- 8 MS. BROWN: Objection. Dose is 9 important to him as it relates to secondhand 10 smoke, is that what the question is asking? 11 MS. PARFITT: No. 12 BY MS. PARFITT: 13 Q I was just reiterating that you, 14 Dr. Diette, have done several secondhand smoke 15 studies, correct? 16 A Yes. 17 Q Okay. And how do you measure the dose 18 in the studies that you have performed? 19 A So different ways, depending upon the 20 studies. So for some studies, it's simple enough 21 to ask, especially if you're talking about an 22 adult, whether or not they've had secondhand smoke 23 exposure from their parents, often broken down by 24 whether it's mother or father. And for some -- 25 some studies, that's a sufficient indicator of a</p>	<p style="text-align: right;">Page 405</p> <p>1 upon which study and which population, we can 2 estimate something about dose based on what 3 their -- what their sort of biomarker is. 4 Q All right. How much have you -- 5 understanding those metrics, for lack of a better 6 word, how much smoke does a patient need to 7 actually inhale? 8 MS. BROWN: For what? 9 BY MS. PARFITT: 10 Q In order to determine whether or not 11 they have been impacted by secondhand smoke. 12 MS. BROWN: Objection to the form. 13 THE WITNESS: That's a complicated 14 question, I guess, because we don't -- at least in 15 our studies, we don't measure -- like I don't know 16 what that means, like how much they inhale. I can 17 tell you, you know, what their absorbed dose is of 18 nicotine, right, which has some implication about 19 how much they might have inhaled, but I don't 20 relate that to like sort of a volume of smokey air 21 or something like that, the way that you might if 22 you were doing like a smoke machine, you know, 23 study. 24 So it's really -- it's implied, right. 25 If you find it in the urine and the blood, they</p>

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<p style="text-align: right;">Page 406</p> <p>1 inhaled it enough in order to get that particular</p> <p>2 fluid level high enough to -- for you to measure</p> <p>3 it. And same with saliva and same with hair.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Okay.</p> <p>6 A I left one out too. We also measure</p> <p>7 airborne nicotine, and so that's another</p> <p>8 indicator. So I was talking about cotinine that's</p> <p>9 measured in -- in the people, but we also have</p> <p>10 nicotine matches, and we'll measure nicotine</p> <p>11 directly in the environment.</p> <p>12 Q Based upon -- I meant to ask this</p> <p>13 earlier. Based upon your study of ovarian cancer</p> <p>14 and talcum powder products that you've done for</p> <p>15 Johnson & Johnson, have you made any of these</p> <p>16 recommendations to Johnson & Johnson as to how --</p> <p>17 what kind of study they could perform in order to</p> <p>18 ascertain dose?</p> <p>19 MS. BROWN: What?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 MS. BROWN: Objection to the form of the</p> <p>22 question.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Let me ask it again.</p> <p>25 A Oh, no, I heard it. I was just -- I</p>	<p style="text-align: right;">Page 408</p> <p>1 couple-year study and, you know, tens of thousands</p> <p>2 of dollars spent doing it?</p> <p>3 MR. LOCKE: Objection.</p> <p>4 MS. BROWN: Objection to the form.</p> <p>5 There are multiple questions in there, Counsel.</p> <p>6 Can you rephrase?</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Do you understand the question?</p> <p>9 A The -- the last part you said -- I'll</p> <p>10 try to paraphrase it so we know we're talking</p> <p>11 about the same thing. I have not -- I have not</p> <p>12 done anything to inform the medical community</p> <p>13 about the findings so far from my -- you know,</p> <p>14 from my work on these cases.</p> <p>15 Q Do you intend to do so?</p> <p>16 A I don't have any active intention to do</p> <p>17 it right now.</p> <p>18 Q Okay. Do you intend to have your report</p> <p>19 peer -- published?</p> <p>20 A It's not in the right format for that.</p> <p>21 Q Okay. Do you intend to do any</p> <p>22 meta-analysis of your work?</p> <p>23 MS. BROWN: Objection to the form.</p> <p>24 THE WITNESS: Not on that -- not on that</p> <p>25 topic.</p>
<p style="text-align: right;">Page 407</p> <p>1 guess the broad answer is no. I mean I haven't</p> <p>2 made any recommendations about studies to Johnson</p> <p>3 & Johnson for -- for anything.</p> <p>4 Q Okay. And the reason I ask is, your</p> <p>5 work appears to be reviewing and surveying the</p> <p>6 literature for Johnson & Johnson in order to give</p> <p>7 litigation opinions on whether or not talcum</p> <p>8 powder products can cause ovarian cancer.</p> <p>9 MR. LOCKE: Objection.</p> <p>10 MS. BROWN: Objection to the form of the</p> <p>11 question.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q Correct?</p> <p>14 A Can you say it again?</p> <p>15 Q Sure.</p> <p>16 A I spaced out a little bit.</p> <p>17 Q No, that's all right. It's getting late</p> <p>18 in the day.</p> <p>19 Your work for Johnson & Johnson appears</p> <p>20 to be surveying the literature, preparing</p> <p>21 litigation reports, and then giving testimony in a</p> <p>22 court that the Johnson & Johnson product is safe.</p> <p>23 And my question for you is, what have</p> <p>24 you done in order to inform the scientific</p> <p>25 community of the results of your -- your now</p>	<p style="text-align: right;">Page 409</p> <p>1 BY MS. PARFITT:</p> <p>2 Q Okay. And if you saw with regard to</p> <p>3 Health Canada, they have given -- they gave</p> <p>4 individuals an opportunity to comment on the work</p> <p>5 that they did and present that to them.</p> <p>6 You saw that, correct?</p> <p>7 A Yes.</p> <p>8 Q Okay. So you had an opportunity as</p> <p>9 someone who's reviewed the literature to write to</p> <p>10 Health Canada and inform them of your concern</p> <p>11 about the manner in which they conducted their</p> <p>12 study. Fair?</p> <p>13 MS. BROWN: Objection to the form, lacks</p> <p>14 foundation.</p> <p>15 THE WITNESS: I guess. I actually don't</p> <p>16 know who they're asking. Like I haven't looked to</p> <p>17 see whether they're looking for people outside of</p> <p>18 Canada.</p> <p>19 I don't even know who they are. I mean</p> <p>20 the only reason I've heard of Health Canada is</p> <p>21 because of this litigation and because something,</p> <p>22 you know, opportunistic came up. But otherwise, I</p> <p>23 mean I wouldn't be talking to Health Canada about</p> <p>24 anything or reading whatever they've written.</p> <p>25 BY MS. PARFITT:</p>

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<p style="text-align: right;">Page 410</p> <p>1 Q Something opportunist came up. Is that 2 the fact that you are being engaged in this 3 litigation -- 4 A No. 5 MS. BROWN: Objection -- 6 BY MS. PARFITT: 7 Q -- as an expert witness? 8 MS. BROWN: Objection to the form. 9 THE WITNESS: Oh, no, I just see -- I 10 think the reason that I have it in front of me is 11 because it -- it seemed to help -- help 12 plaintiffs' experts to be able to say something 13 else about this -- this story. And if -- if it 14 had said something else, then I probably wouldn't 15 even have heard about it. 16 BY MS. PARFITT: 17 Q Okay. This story, Dr. Diette, is about 18 women who are dying of ovarian cancer -- 19 MS. BROWN: Careful -- what's the 20 question? 21 BY MS. PARFITT: 22 Q -- having been exposed to talcum powder 23 products. 24 Do you understand that? 25 MR. LOCKE: Objection.</p>	<p style="text-align: right;">Page 412</p> <p>1 MS. BROWN: Objection. 2 THE WITNESS: The only studies I've seen 3 are the ones that -- I think that were cited by -- 4 by IARC with -- if that's what we're talking 5 about, is like women who were about to have 6 surgery for some other reason and -- and different 7 things placed either in their uterus or vagina, 8 although not necessarily talc. I mean all kinds 9 of things, you know, carbon particles, 10 radiolabeled particles, different things that 11 aren't talc. 12 (Counsel conferring.) 13 BY MS. PARFITT: 14 Q So sitting here today, is it your 15 testimony that you have not reviewed or seen in 16 the medical literature that particles of talc can 17 migrate to the ovaries, lymph nodes, of a woman's 18 body? 19 MS. BROWN: Objection to the form of the 20 question. 21 MR. LOCKE: Objection. 22 THE WITNESS: So -- so the study would 23 be one where somebody applied talc to the perineum 24 and then demonstrated that it migrated from there 25 to the ovaries or into some lymph node somewhere?</p>
<p style="text-align: right;">Page 411</p> <p>1 MS. BROWN: Objection to the form of the 2 question. 3 THE WITNESS: I understand the general 4 notion is about ovarian cancer and whether there 5 is or is not a risk from talcum powder. 6 BY MS. PARFITT: 7 Q I appreciate that. 8 All right, Dr. Diette, do you agree that 9 there is scientific evidence published in the 10 peer-reviewed journal that talcum powder products 11 can migrate from the vagina to the peritoneal 12 capacity up through the ovaries? 13 MS. BROWN: Objection to the form. 14 MR. LOCKE: Objection. 15 THE WITNESS: From the perineum? 16 BY MS. PARFITT: 17 Q From the perineum. 18 MS. BROWN: Objection. 19 THE WITNESS: I have not seen that. 20 BY MS. PARFITT: 21 Q Okay. Do you have -- have you seen in 22 your review of the literature that talcum powder 23 products can migrate from the vagina to the 24 ovaries? 25 MR. LOCKE: Objection.</p>	<p style="text-align: right;">Page 413</p> <p>1 BY MS. PARFITT: 2 Q That's right. 3 A I have not seen that study. 4 Q Okay. You've read the Schildkraut 5 study, correct? 6 A Yes. 7 Q Okay. Do you agree with the authors of 8 the Schildkraut study that chronic inflammation 9 resulting from the use of exposure to baby powder, 10 whether through inhalation or through a 11 transvaginal route, may lead to an increased risk 12 of ovarian cancer? 13 MR. LOCKE: Objection. 14 MS. BROWN: Objection to the form of the 15 question. 16 THE WITNESS: I've read the study. I'd 17 like to see whether that's in the introduction or 18 the conclusion. 19 BY MS. PARFITT: 20 Q Okay. Let me show you Schildkraut. 21 A Because it's certainly not a conclusion 22 of their study. 23 (Diette Exhibit No. 29 was marked 24 for identification.) 25 MS. BROWN: Do you guys want a number on</p>

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<p style="text-align: right;">Page 414</p> <p>1 this?</p> <p>2 MS. PARFITT: Sure. What number are we</p> <p>3 up to?</p> <p>4 MS. BROWN: Oh, 29. I'm sorry. It's</p> <p>5 there. My bad.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q Do you have that in front of you,</p> <p>8 Doctor?</p> <p>9 A I do.</p> <p>10 Q Okay. And if I can direct your</p> <p>11 attention to pages 14, 16.</p> <p>12 A Got you.</p> <p>13 Q Do you have that?</p> <p>14 Do you see where the authors state:</p> <p>15 "Lung inhalation of powder could be a biologically</p> <p>16 plausible mechanism for the association between</p> <p>17 nongenital powder use and increased EOC risk,</p> <p>18 particularly non-serous EOC."</p> <p>19 Do you see that?</p> <p>20 A I do. It's the top of the first column</p> <p>21 in the -- the rest of the incomplete paragraph.</p> <p>22 Q Okay. Do you see that?</p> <p>23 A I do.</p> <p>24 Q Okay. Do you agree with that?</p> <p>25 MR. LOCKE: Objection.</p>	<p style="text-align: right;">Page 416</p> <p>1 MR. LOCKE: Objection.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Okay. Do you agree that there is</p> <p>4 reliable scientific literature in the</p> <p>5 peer-reviewed studies to support that it is</p> <p>6 biologically plausible for talc products to</p> <p>7 migrate from the vagina to the ovaries following</p> <p>8 perineal application?</p> <p>9 A I'm not aware of that study that has</p> <p>10 shown that.</p> <p>11 Q Have you seen the Penninkilampi study?</p> <p>12 A Oh.</p> <p>13 MS. BROWN: Objection.</p> <p>14 THE WITNESS: Yes, I have.</p> <p>15 BY MS. PARFITT:</p> <p>16 Q Okay. Why don't we take a look at that.</p> <p>17 Let's pull it up, and we'll make it</p> <p>18 Exhibit No. 30.</p> <p>19 (Diette Exhibit No. 30 was marked</p> <p>20 for identification.)</p> <p>21 BY MS. PARFITT:</p> <p>22 Q Right here. And if I may, Doctor, let</p> <p>23 me direct your attention to the discussion section</p> <p>24 of Penninkilampi on page 45.</p> <p>25 A Page 45?</p>
<p style="text-align: right;">Page 415</p> <p>1 THE WITNESS: Only -- well, no. Only in</p> <p>2 the broadest sense that lots of things could be,</p> <p>3 but not because there's any evidence to show that</p> <p>4 inhalation of powder is a way to get to the</p> <p>5 ovaries.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q All right. So you dispute that</p> <p>8 inhalation of talcum powder products can cause</p> <p>9 ovarian cancer. Is that your testimony?</p> <p>10 A Inhalation?</p> <p>11 Q Inhalation.</p> <p>12 A I haven't seen any evidence that it can.</p> <p>13 I mean there's not affirmative evidence to say</p> <p>14 that it absolutely can't, but there's no evidence</p> <p>15 that there's been talcum powder inhaled, leading</p> <p>16 to other -- other diseases along the way, and I</p> <p>17 haven't seen any study that has shown that it can</p> <p>18 migrate from the lungs to the ovaries. And so --</p> <p>19 I mean people could say that, but it's not based</p> <p>20 on -- on studies.</p> <p>21 Q Does the fact that talcum powder</p> <p>22 products can be inhaled support a biologically</p> <p>23 plausible mechanism for talcum powder products to</p> <p>24 cause ovarian cancer?</p> <p>25 A No.</p>	<p style="text-align: right;">Page 417</p> <p>1 Q 45.</p> <p>2 A Yep.</p> <p>3 Q Do you have that?</p> <p>4 A I'm there, yep.</p> <p>5 Q Okay. It says: "The present</p> <p>6 meta-analysis" -- and it is meta-analysis,</p> <p>7 correct?</p> <p>8 A Yeah, part of this study is a</p> <p>9 meta-analysis.</p> <p>10 Q "The present meta-analysis reports a</p> <p>11 positive association between perineal talc use and</p> <p>12 ovarian cancer, specifically of the serous and</p> <p>13 endometriode -- and endometrioid histology site --</p> <p>14 subtypes. The mechanism by which perineal talc</p> <p>15 use may increase the risk of ovarian cancer is</p> <p>16 uncertain. It has been previously proposed that</p> <p>17 talc as a foreign body may ascend from the vagina</p> <p>18 through to the uterine tubes and instigate a</p> <p>19 chronic inflammatory response, which may</p> <p>20 predispose to the development of ovarian cancer."</p> <p>21 Did I read that correctly?</p> <p>22 A You did.</p> <p>23 Q Okay. Do you agree with that?</p> <p>24 MR. LOCKE: Objection.</p> <p>25 MS. BROWN: Objection to the form.</p>

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<p style="text-align: right;">Page 418</p> <p>1 THE WITNESS: So -- so I agree with a 2 lot of this, right. So I agree that the mechanism 3 is uncertain. Right. I agree that it has been 4 previously proposed 20 years ago by the citation 5 that they have that that may ascend from the 6 vagina, and instigate a chronic inflammation 7 response. 8 They don't cite anything more modern 9 than that one from 20 years ago, though. And 10 where it talks about it may be mutagenic and 11 promote carcinogenesis -- 12 BY MS. PARFITT: 13 Q Correct. 14 A -- I don't -- I don't think that's well 15 supported either. 16 Q Is migration of talc a biologically 17 plausible mechanism by which talc can reach the 18 ovaries? 19 MS. BROWN: Objection to the form. 20 MR. LOCKE: Objection. 21 THE WITNESS: If it were true, it could 22 be supportive of that. But I don't see any -- any 23 evidence that it's true. 24 BY MS. PARFITT: 25 Q Is biological plausibility essential for</p>	<p style="text-align: right;">Page 420</p> <p>1 inflammatory hypothesis, as repeated exposure 2 would induce a longer period of chronic 3 inflammation, and therefore should increase the 4 predisposition to the development of ovarian 5 cancer." 6 Did I read that correctly? 7 A You did. 8 Q All right. Do you agree with that 9 statement, that chronic inflammation as a 10 biologically plausible hypothesis could induce 11 carcinogenicity? 12 MR. LOCKE: Objection. 13 MS. BROWN: Counsel, are you 14 intentionally not reading the rest of that 15 paragraph? 16 MS. PARFITT: No, I -- I'm getting 17 there. 18 MS. BROWN: Okay. 19 MS. PARFITT: Yeah. 20 THE WITNESS: Well, I disagree with the 21 fact that the small difference between 3600, plus 22 or minus, lifetime applications supports a -- an 23 inflammatory theory, because that's got nothing 24 too do with inflammation. It's really just a -- a 25 total number of applications.</p>
<p style="text-align: right;">Page 419</p> <p>1 causality? 2 A No, it's -- it's one important criterion 3 to consider. 4 Q Does biological plausibility mean it 5 must be proved? 6 MS. BROWN: Objection. 7 THE WITNESS: And I assume we're talking 8 about in the context of a Bradford Hill? 9 BY MS. PARFITT: 10 Q Correct. 11 A Yeah, so -- so the answer is, no, it 12 doesn't have to be proved. 13 Q Look at the lower right-hand corner of 14 that article. 15 MS. BROWN: Are we done with that 16 paragraph, Counsel? 17 MS. PARFITT: We are. Thank you very 18 much, yeah. 19 BY MS. PARFITT: 20 Q And if you will go down to the lower 21 right, it starts with "We also found." 22 A Okay. 23 Q Do you see that? 24 Okay. It says: "This finding also 25 supports the chronic" -- I'm sorry -- "chronic</p>	<p style="text-align: right;">Page 421</p> <p>1 BY MS. PARFITT: 2 Q Perhaps I can simplify my answer. Do 3 you have an opinion as to whether or not chronic 4 inflammation can be a biologically plausible 5 method for promoting carcinogenesis? 6 MS. BROWN: Objection to the form. 7 THE WITNESS: In -- in all kinds of 8 cancer or ovarian cancer? 9 BY MS. PARFITT: 10 Q In ovarian cancer. 11 A So I -- I don't think there's strong 12 evidence to support that. 13 Q Is there evidence at all? 14 MS. BROWN: Let him finish. 15 THE WITNESS: So not much. I mean 16 there's -- I know that folks have looked at, you 17 know, whether NSAIDS and aspirin, whether that use 18 would lead to a limitation in risk, and it seems 19 like the -- the findings are kind of mixed. And 20 sometimes aspirin in a particular dose is 21 protective and aspirin of another dose is not. 22 That NSAIDS are sometimes protective, but mostly 23 not. 24 Since preparing my report, I saw 25 Dr. Shih -- Shih's report talking about the stick</p>

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<p style="text-align: right;">Page 422</p> <p>1 cells, like these precursor cells, and -- and at</p> <p>2 least, you know, from histologic specimens, not</p> <p>3 seeing evidence of inflammation. And I haven't</p> <p>4 really seen much that -- that would confirm that</p> <p>5 there's a link between chronic inflammation.</p> <p>6 BY MS. PARFITT:</p> <p>7 Q What I'm asking you is, based upon your</p> <p>8 review, Dr. Diette, have you seen anything in the</p> <p>9 peer-reviewed literature that there are</p> <p>10 biologically plausible mechanisms of talc's</p> <p>11 carcinogenicity demonstrated by chronic</p> <p>12 inflammation from migration of the talc to the</p> <p>13 ovaries?</p> <p>14 MS. BROWN: Objection. I don't</p> <p>15 understand that question.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: Would you --</p> <p>18 BY MS. PARFITT:</p> <p>19 Q The question -- let me rephrase it.</p> <p>20 A Okay.</p> <p>21 Q Is there -- are there studies in the</p> <p>22 peer-reviewed literature that support an</p> <p>23 association of inflammation and increased risk of</p> <p>24 ovarian cancer?</p> <p>25 MS. BROWN: Objection to the form, asked</p>	<p style="text-align: right;">Page 424</p> <p>1 BY MS. PARFITT:</p> <p>2 Q T-A-H-E-R.</p> <p>3 A Oh.</p> <p>4 Q 2018.</p> <p>5 A Sorry, I was saying Taher.</p> <p>6 Q No, no problem.</p> <p>7 A But I don't now how you --</p> <p>8 Q You could be right on that. Probably</p> <p>9 are.</p> <p>10 A I don't know.</p> <p>11 I did.</p> <p>12 Q Do you see where Taher authors found</p> <p>13 that there was biologically plausible evidence of</p> <p>14 inflammation from talc exposure?</p> <p>15 MS. BROWN: Objection. Counsel, can we</p> <p>16 see the article if you want to ask him about it?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q You've read the article. Do you know</p> <p>20 the answer to that?</p> <p>21 MS. BROWN: But it's not a memory test.</p> <p>22 MS. PARFITT: No, it's not, but perhaps</p> <p>23 he can answer. I didn't ask you the question.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Do you know the answer to that?</p>
<p style="text-align: right;">Page 423</p> <p>1 and answered.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Is there something in the literature?</p> <p>4 MS. BROWN: Objection.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Not whether there is a lot or a little.</p> <p>7 Is there anything in the peer-reviewed literature</p> <p>8 that you've seen that supports an association</p> <p>9 between inflammation and an increased risk of</p> <p>10 ovarian cancer?</p> <p>11 MS. BROWN: Objection to the form.</p> <p>12 THE WITNESS: I've seen the paper where</p> <p>13 C-reactive protein in the serum popped out of</p> <p>14 dozens of different markers of inflammation and</p> <p>15 predated the diagnosis of ovarian cancer.</p> <p>16 I guess I haven't really seen something</p> <p>17 that shows that chronic inflammation in the</p> <p>18 ovaries is -- is a precursor to ovarian cancer or</p> <p>19 that talc induces that particular chronic</p> <p>20 inflammation that would in turn lead to cancer.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q Have you read Taher? You've read the</p> <p>23 Taher study, correct?</p> <p>24 MR. LOCKE: Objection.</p> <p>25 THE WITNESS: How do you spell it?</p>	<p style="text-align: right;">Page 425</p> <p>1 A Well, the paper wasn't about that, so I</p> <p>2 don't -- I don't remember whether there was sort</p> <p>3 of a preamble thing, but they -- they weren't</p> <p>4 really analyzing that. They were doing a</p> <p>5 meta-analysis, you know, sort of combining the epi</p> <p>6 studies. So, I mean, I don't remember what their</p> <p>7 statement was, but when you --</p> <p>8 Q All right. Did you --</p> <p>9 A I'm sorry, I just want to say, but if</p> <p>10 you say that they found it, by finding it, I don't</p> <p>11 think they demonstrated it or it was a finding</p> <p>12 from their study per se.</p> <p>13 Q Okay. Have you read Langseth, 2008?</p> <p>14 A Langseth, 2008?</p> <p>15 Q Correct.</p> <p>16 A Is that a meta-analysis?</p> <p>17 Q Correct.</p> <p>18 A Yes.</p> <p>19 Q All right. And do you see where the</p> <p>20 Langseth authors also found migration and -- and</p> <p>21 concluded that there was chronic inflammation that</p> <p>22 was biologically plausible?</p> <p>23 MS. BROWN: No, I -- I object. If</p> <p>24 you're going to quote articles --</p> <p>25 BY MS. PARFITT:</p>

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<p style="text-align: right;">Page 426</p> <p>1 Q Do you remember?</p> <p>2 MS. BROWN: -- I would request the</p> <p>3 article.</p> <p>4 MS. PARFITT: I can do that.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Do you know, Doctor?</p> <p>7 A I don't remember what they said.</p> <p>8 (Counsel conferring.)</p> <p>9 MS. PARFITT: Doctor, if we can take a</p> <p>10 quick break here --</p> <p>11 THE WITNESS: Sure.</p> <p>12 MS. PARFITT: -- right now, so maybe I</p> <p>13 can --</p> <p>14 THE WITNESS: Yeah, it's a good time.</p> <p>15 MS. PARFITT: -- shorten things.</p> <p>16 THE VIDEOGRAPHER: The time is 4:59 p.m.</p> <p>17 We're going off the record.</p> <p>18 (Recess.)</p> <p>19 THE VIDEOGRAPHER: The time is 5:12 p.m.</p> <p>20 and we're back on the record.</p> <p>21 MS. PARFITT: I apologize.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Dr. Diette, and I apologize, I have only</p> <p>24 one copy that isn't marked up, so we're going to</p> <p>25 have to put this and substitute it on the -- on</p>	<p style="text-align: right;">Page 428</p> <p>1 He doesn't have the article.</p> <p>2 MS. PARFITT: That's fine.</p> <p>3 MS. BROWN: And he's never read it.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Look at the abstract, first sentence.</p> <p>6 It says: "Perineal talc use is associated with</p> <p>7 ovarian carcinoma in many case-control studies.</p> <p>8 Such talc may migrate to pelvic organs and</p> <p>9 regional lymph nodes, with both clinical and legal</p> <p>10 significance."</p> <p>11 Did I read that correctly?</p> <p>12 A Yes.</p> <p>13 Q All right. Would it be -- I believe you</p> <p>14 had some concerns about the Heller study that we</p> <p>15 talked about earlier because it involved some</p> <p>16 unexposed -- what you testified were unexposed</p> <p>17 women.</p> <p>18 MS. BROWN: Objection to the form.</p> <p>19 THE WITNESS: Correct, women who</p> <p>20 reported not being perineal talc users.</p> <p>21 BY MS. PARFITT:</p> <p>22 Q Right. Okay. You understand in this</p> <p>23 study that what Drs. McDonald and Godleski were</p> <p>24 doing were looking at particles in exposed women.</p> <p>25 MS. BROWN: No, he doesn't understand</p>
<p style="text-align: right;">Page 427</p> <p>1 the ELMO, if I may. We've done pretty good with</p> <p>2 copies all day today.</p> <p>3 So here we go.</p> <p>4 MR. ROSEN: This will be Exhibit 31.</p> <p>5 (Diette Exhibit No. 31 was marked</p> <p>6 for identification.)</p> <p>7 BY MS. PARFITT:</p> <p>8 Q All right. Dr. Diette, this is an</p> <p>9 article from Ultrastructural Pathology, and it's</p> <p>10 entitled "Correlative polarizing light and</p> <p>11 scanning electron microscopy for the assessment of</p> <p>12 talc in pelvic region lymph nodes."</p> <p>13 Do you see that?</p> <p>14 A I do.</p> <p>15 Q And the lead author is Dr. McDonald,</p> <p>16 along with Cramer and Godleski, and others.</p> <p>17 Do you see that?</p> <p>18 A I do.</p> <p>19 Q All right. This is published in 2019.</p> <p>20 Have you had an opportunity to review</p> <p>21 this article?</p> <p>22 A I have not seen this one.</p> <p>23 Q Okay. I just have one question about</p> <p>24 it. And if --</p> <p>25 MS. BROWN: Well, I'm going to object.</p>	<p style="text-align: right;">Page 429</p> <p>1 that because he doesn't have the study and he</p> <p>2 hasn't read it. I object. It's not fair.</p> <p>3 THE WITNESS: I honestly have no idea</p> <p>4 what they've done.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q Okay. Well, do you dispute that talc</p> <p>7 particles can migrate to the pelvic organs and</p> <p>8 regional lymph nodes?</p> <p>9 A I don't -- I don't know.</p> <p>10 MR. LOCKE: Asked and answered.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q You don't know. You don't know. You</p> <p>13 don't know one way or another?</p> <p>14 MS. BROWN: Objection, misstates his</p> <p>15 private -- his prior testimony.</p> <p>16 THE WITNESS: Migrate from where to</p> <p>17 where? From --</p> <p>18 BY MS. PARFITT:</p> <p>19 Q It says right here: "Talc may migrate</p> <p>20 to pelvic organs and regional lymph nodes."</p> <p>21 MS. BROWN: Right, but he can't --</p> <p>22 THE WITNESS: Oh, I saw the "to," but I</p> <p>23 don't see the "from."</p> <p>24 BY MS. PARFITT:</p> <p>25 Q Does it make a difference to you?</p>

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<p>1 MS. BROWN: Of course.</p> <p>2 BY MS. PARFITT:</p> <p>3 Q If it's from the vaginal area to the</p> <p>4 ovaries and the lymph nodes, does that make a</p> <p>5 difference whether --</p> <p>6 MR. LOCKE: Objection.</p> <p>7 MS. BROWN: Objection to the form, lacks</p> <p>8 foundation, calls for speculation about a document</p> <p>9 he told you he's never read.</p> <p>10 MR. LOCKE: Does the witness have a</p> <p>11 copy?</p> <p>12 MS. BROWN: No. That's the objection.</p> <p>13 MS. PARFITT: Tom, we didn't -- we only</p> <p>14 have one copy of it.</p> <p>15 MR. LOCKE: I think you need to disclose</p> <p>16 to the witness that three of these authors are</p> <p>17 paid experts, et cetera --</p> <p>18 MS. PARFITT: Tom, Tom, Tom, Tom.</p> <p>19 MR. LOCKE: Come on.</p> <p>20 MS. BROWN: No, but to be fair, you</p> <p>21 guys, if you want to ask him questions, he's got</p> <p>22 to look at it. I'm going to take it off the ELMO</p> <p>23 and give it to him if you're going to continue</p> <p>24 asking him questions.</p> <p>25 BY MS. PARFITT:</p>	<p>1 You had testified earlier that you</p> <p>2 disagree with Health Canada when they state that</p> <p>3 talc can migrate to the ovaries; is that correct?</p> <p>4 MR. LOCKE: Objection.</p> <p>5 MS. BROWN: Objection. Misstates prior</p> <p>6 testimony. I don't even think he said that.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q Well, let me ask you. In the Health</p> <p>9 Canada report, they discuss the fact that it is</p> <p>10 biologically plausible for talc to migrate to the</p> <p>11 ovaries and then cause an inflammatory process.</p> <p>12 Do you agree or disagree with that?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 MS. BROWN: Objection. Lacks</p> <p>15 foundation. Do you want to show him where they</p> <p>16 said that?</p> <p>17 THE WITNESS: I don't remember their</p> <p>18 statement about that.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q You don't. Okay.</p> <p>21 How about this statement. Go down to --</p> <p>22 I believe it's -- one, two, three -- the third</p> <p>23 paragraph. Do you see that? It starts with</p> <p>24 "While."</p> <p>25 A No.</p>
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<p>1 Q I'm not going to ask him any more</p> <p>2 questions on it, Doctor.</p> <p>3 A Okay. Thank you.</p> <p>4 Q All right. Let me show you --</p> <p>5 MR. LOCKE: Come on. Give him -- if</p> <p>6 you're going to give him -- if you're going to ask</p> <p>7 him about it --</p> <p>8 MR. TISI: You're not even on record.</p> <p>9 MS. PARFITT: Tom, it was just --</p> <p>10 MS. BROWN: Hey, hey, hey, guys. It's</p> <p>11 the end of the day.</p> <p>12 MS. PARFITT: Okay. Let's don't --</p> <p>13 MS. BROWN: Let's get through this.</p> <p>14 (Diette Exhibit No. 32 was marked</p> <p>15 for identification.)</p> <p>16 BY MS. PARFITT:</p> <p>17 Q 32. Let me show you what's been marked</p> <p>18 as Plaintiffs' Exhibit 32.</p> <p>19 I need a copy. There you go. Sorry.</p> <p>20 A Thank you.</p> <p>21 Q Okay. You previously testified that you</p> <p>22 -- take a look at it. You read this before, the</p> <p>23 FDA letter 2014?</p> <p>24 A I've seen this.</p> <p>25 Q Okay. Very good.</p>	<p>1 Q No?</p> <p>2 A Oh, I'm on a different page.</p> <p>3 Q I'm sorry. Page 5. Page 5.</p> <p>4 A Okay.</p> <p>5 Q Okay. "While there exists no direct</p> <p>6 proof of talc and ovarian carcinogenesis, the</p> <p>7 potential for particles to migrate from the</p> <p>8 perineum into the vagina to the peritoneal cavity</p> <p>9 is indisputable."</p> <p>10 Do you see that?</p> <p>11 A I do.</p> <p>12 Q Okay. Do you agree with the FDA?</p> <p>13 MS. BROWN: Objection to the form.</p> <p>14 THE WITNESS: So there's no citation for</p> <p>15 that. I don't know how they get -- I mean I don't</p> <p>16 know why they make that statement, and I -- it</p> <p>17 certainly doesn't seem to be indisputable, because</p> <p>18 there -- several of the articles that we've looked</p> <p>19 at today and others say it's not clear what the</p> <p>20 mechanism is or the biologic plausibility. So</p> <p>21 it's -- it's obviously disputable, at the very</p> <p>22 least, but there's no citation, so it's hard to</p> <p>23 know how to -- how to process this.</p> <p>24 BY MS. PARFITT:</p> <p>25 Q If this is the FDA's position with</p>

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<p style="text-align: right;">Page 434</p> <p>1 regard to whether or not talc can migrate, do you 2 dispute that?</p> <p>3 MS. BROWN: Objection. Misstates the 4 document.</p> <p>5 THE WITNESS: I don't -- I don't dispute 6 that they said it obviously, because it's right 7 here, but there's just no citation for it, and 8 there's no information that tells who in 9 particular thinks that.</p> <p>10 BY MS. PARFITT:</p> <p>11 Q Well, the Food and Drug Administration 12 is our regulatory body here in the United States, 13 correct?</p> <p>14 A It is one.</p> <p>15 MR. LOCKE: Objection.</p> <p>16 BY MS. PARFITT:</p> <p>17 Q All right. Would you agree that 18 dissemination of information that is accurate and 19 truthful is -- is something that they would 20 probably take quite seriously? Would you agree?</p> <p>21 MS. BROWN: Objection.</p> <p>22 THE WITNESS: I -- I hope so.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q Right. And would you agree that the FDA 25 would not be disseminating information about the</p>	<p style="text-align: right;">Page 436</p> <p>1 think my answer was along the lines of I haven't 2 seen a study that shows that that's true.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q We talked about Schildkraut. We talked 5 about Schildkraut, didn't we?</p> <p>6 A Yeah, they didn't show that either, 7 though.</p> <p>8 Q When you say they didn't show it, have 9 they opined in medical -- or let me ask you this 10 question. I see the disconnect.</p> <p>11 Is there evidence contained in 12 peer-reviewed scientific articles wherein it is 13 stated that talcum powder products can migrate to 14 the ovaries?</p> <p>15 MS. BROWN: Objection.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 MS. BROWN: Misstates everything we've 18 looked at and his testimony.</p> <p>19 THE WITNESS: I think there's been 20 opinions of different people in different articles 21 that are both supportive and not supportive of 22 that statement.</p> <p>23 BY MS. PARFITT:</p> <p>24 Q All right. So you've seen scientific 25 writers who have said talc can migrate to the</p>
<p style="text-align: right;">Page 435</p> <p>1 potential for particulates to migrate from the 2 perineum, the vagina to the peritoneal cavity, and 3 say it's indisputable if they didn't have some 4 evidence?</p> <p>5 MS. BROWN: Objection. Calls for 6 speculation.</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: I don't know why they 9 wrote it. I just think it would be odd to find 10 that the FDA knew this, and it's not out there 11 generally otherwise. I mean I don't -- I don't 12 know what they considered.</p> <p>13 BY MS. PARFITT:</p> <p>14 Q When you say it's not out there 15 generally, we talked today about several 16 peer-reviewed articles that have in fact talked 17 about talcum powder part- -- particles migrating 18 to the ovaries, have we not?</p> <p>19 MS. BROWN: Objection. We have not.</p> <p>20 THE WITNESS: No, I was going to say, I 21 mean, you've said that a lot, but I mean -- but we 22 haven't looked at a study that shows that. I mean 23 we've talked about whether -- whether or not talc 24 applied to the perineum has been shown to migrate 25 to the ovaries, and a bunch of questions back, I</p>	<p style="text-align: right;">Page 437</p> <p>1 ovaries, and you've seen scientific articles that 2 say that's more questionable. Is that fair?</p> <p>3 MS. BROWN: Objection. Not fair.</p> <p>4 Misstates prior --</p> <p>5 THE WITNESS: It's sort of fair, but I 6 can't find anybody who's actually shown that it's 7 true. I mean, you know, people may write that, 8 but I mean I haven't seen a study that's shown 9 that you can actually apply talc to the perineum 10 and then find it in the ovaries.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q Okay. Let me show you what we'll have 13 marked as exhibit -- oh, thank you. 14 (Counsel conferring.)</p> <p>15 BY MS. PARFITT:</p> <p>16 Q It's the end of the day, and we are 17 running out of copies, Doctor.</p> <p>18 Let me show you -- 19 (Diette Exhibit No. 33 was marked 20 for identification.)</p> <p>21 MR. ROSEN: Exhibit 33.</p> <p>22 MS. PARFITT: Beg your pardon? 33?</p> <p>23 THE WITNESS: This one says 32 on it.</p> <p>24 MR. ROSEN: Ah, you're correct.</p> <p>25 BY MS. PARFITT:</p>

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<p style="text-align: right;">Page 438</p> <p>1 Q So I'm going to share this with you, 2 and -- actually, if we could put it on the ELMO, 3 and then I will give it to you so I can at least 4 identify it for counsel. 5 Is that fair? 6 A Yeah. We will see how it goes. 7 Q All right. Let me show you -- it is 8 marked September 30th, 2004, and I will represent 9 that it is to Bill Ashton from Richard Zazenski, 10 and it's a Luzenac document. 11 MS. BROWN: What? I'm going to object 12 on form and foundation. 13 BY MS. PARFITT: 14 Q Okay. Can you see that, Doctor? I 15 don't want to strain your eyes too much. 16 MS. BROWN: No, we need to give him -- 17 he's never seen it. He hasn't reviewed it. His 18 opinions are not based on it. If you want to ask 19 him questions about it, he needs to hold it and 20 look at it. 21 BY MS. PARFITT: 22 Q I'm going to give it to you. I'm going 23 to let you hold it in one moment. 24 Dr. Diette, this is a document I will 25 represent that's dated September 30, 2004, and</p>	<p style="text-align: right;">Page 440</p> <p>1 Take a moment and take a look at that, to eyeball 2 that. 3 MS. BROWN: Take as long as you need to 4 inform your response -- 5 MS. PARFITT: It's a one-page document. 6 MR. LOCKE: No. This -- this is a 7 document that he hasn't seen before. 8 MS. PARFITT: That's correct. 9 MR. LOCKE: Why don't we go off the 10 record. 11 MS. PARFITT: It's one page, Doctor. 12 MS. BROWN: Right, and that's just fair. 13 MS. MILLER: If you're going to ask him 14 questions about what you just threw out there -- 15 MS. BROWN: That's fine. That's fine, 16 but you understand there's no foundation. He's 17 never relied it. 18 MS. PARFITT: Okay, guys -- 19 MS. BROWN: So if we want to ask 20 questions -- 21 THE REPORTER: Excuse me. 22 MS. PARFITT: I'm not having him -- 23 whoa, whoa. 24 (A discussion was held off the record.) 25 BY MS. PARFITT:</p>
<p style="text-align: right;">Page 439</p> <p>1 that would have preceded any litigation. 2 And it states: "Bill, I came across 3 this paper this morning published in the April 4 2004 journal Human Reproduction, an official 5 journal of the European Society for Human 6 Reproduction and Embryology. It offers some 7 compelling evidence in support of the migration 8 hypothesis. Combine this evidence with the theory 9 that the talc deposition on the ovarian epithelium 10 initiates epithelium inflammation, which leads to 11 epithelium carcinogenesis, and you have a 12 potential formula for NTP classifying talc as a 13 causative agent in ovarian cancer." 14 Now, did I read that correctly? 15 A Yes. 16 Q So let me -- because counsel wants you 17 to hold it, let me have you take -- 18 MS. BROWN: Well, only if you're going 19 to ask him questions about it. 20 MS. PARFITT: I am. I am. But I can't 21 do both. 22 BY MS. PARFITT: 23 Q I've got to hand it to you because she 24 says she wants you to hold it. 25 And attached to that is the article.</p>	<p style="text-align: right;">Page 441</p> <p>1 Q Dr. Diette, I'm simply referring to the 2 cover letter. 3 A Oh. 4 Q And that's all, just one page. Do you 5 see that? 6 A I do. 7 Q Okay. And that's what I just read into 8 the record. Do you see that? 9 A I do. 10 Q Okay. And do you see back in 2004, 11 there was information with regard -- and I have to 12 see it, I can't be -- sorry. I can't memorize it 13 either. 14 So you see back in 2004, the company's 15 being advised that there is indeed literature 16 compelling evidence in support of a migration 17 hypothesis -- 18 MS. BROWN: Object. 19 BY MS. PARFITT: 20 Q -- that was shared between the two 21 companies. 22 Did J&J ever share with you this 23 document that they had in their company files that 24 they had support -- actually compelling evidence 25 of support of the migration hypothesis?</p>

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<p style="text-align: right;">Page 442</p> <p>1 MS. BROWN: Objection to the speech, 2 lacks foundation. I also believe that's an Imerys 3 document. 4 THE WITNESS: So a few things, right. 5 So one is I -- I've never seen that, so I don't 6 even know what it is. I don't know who those 7 people are. That -- I don't know what their 8 qualifications are to consider something to be 9 compelling evidence or if that's the word that was 10 used. 11 BY MS. PARFITT: 12 Q Mm-hmm. 13 A I have not seen the article that's 14 attached to the back of it. 15 Q Okay. 16 A But it's hard to say much about that. 17 Q Yes. 18 Let me show you what we will have marked 19 as Exhibit 34, and I'll represent to you it's an 20 article by Roberta Ness, "Possible Role of Ovarian 21 Epithelial Inflammation." 22 (Diette Exhibit No. 34 was marked 23 for identification.) 24 BY MS. PARFITT: 25 Q Have you seen this article before?</p>	<p style="text-align: right;">Page 444</p> <p>1 it -- that this -- is this an e-mail or a fax? It 2 has something from Ness's paper or Ness's paper 3 has something from this -- 4 BY MS. PARFITT: 5 Q They have something from Ness's paper, 6 correct. 7 MS. BROWN: Well, objection. 8 THE WITNESS: But this is -- 9 MS. BROWN: Don't -- don't speculate. 10 No one wants you to guess. 11 MS. PARFITT: So we won't talk about -- 12 MS. BROWN: Just wait for a question, 13 and we'll do the best we can. 14 BY MS. PARFITT: 15 Q Okay. Do you see on the first page of 16 Dr. Ness's article, in the left-hand column 17 towards the bottom, where Dr. Ness states: 18 "Inflammation entails cell damage, oxidative 19 stress, and elevations of cytokines and 20 prostaglandins, all of which may be mutagenic. 21 The possibility that inflammation is a 22 pathophysiological contributor to the development 23 of ovarian cancer suggests a directed approach to 24 future research." 25 Do you see that?</p>
<p style="text-align: right;">Page 443</p> <p>1 A I have. 2 Q Okay. Do you see on page 2 -- 3 MS. PARFITT: Where is the other one? 4 (Counsel conferring.) 5 BY MS. PARFITT: 6 Q If I could -- you have in front of you 7 the Zazenski -- thank you. 8 Okay. Now, do you see the graph, I'll 9 call it, it's the chart there on Zazenski? And 10 then look at Figure No. 1. Do you see that, 11 "Inflammation is a common mechanism underlying 12 ovarian cancer"? 13 A I do. 14 Q Okay. And do you see that -- you can 15 look at it. Do you see that that's the same 16 figure in the Zazenski letter as it is in 17 Dr. Ness's letter? Do you see that? 18 MS. BROWN: Objection to the form, lacks 19 foundation. 20 BY MS. PARFITT: 21 Q Or Dr. Ness's report. 22 MS. BROWN: Same objection. 23 THE WITNESS: I mean it -- it looks the 24 same. 25 But what does that mean? Does that mean</p>	<p style="text-align: right;">Page 445</p> <p>1 A I do. 2 Q Okay. Do you agree with that statement? 3 MR. LOCKE: Objection. 4 MS. BROWN: Objection to the form. 5 THE WITNESS: So, I haven't read this 6 article in a while. It is from about 20 years 7 ago. And so I don't know if 20 years ago that was 8 a reasonable thing to consider, but it sounds as 9 if 20 years have gone by and this still hasn't 10 been proven. And so whether I agree with it still 11 now, I'm not sure. I'm not sure if it would be a 12 fruitful endeavor or not. 13 BY MS. PARFITT: 14 Q Does biological plausibility mean that 15 something must be proven? 16 MR. LOCKE: Objection. Asked -- 17 MS. BROWN: Objection. Asked and 18 answered. 19 THE WITNESS: It doesn't mean that 20 it's -- that it's been proven, but it's one of the 21 ways to provide supportive information about 22 whether or not an observed association is causal 23 or not. 24 BY MS. PARFITT: 25 Q Okay. So you agree that you do not --</p>

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<p style="text-align: right;">Page 446</p> <p>1 one does not need to prove mechanism in order to 2 find causality, correct? 3 A I need to prove -- 4 MR. LOCKE: Objection. 5 MS. BROWN: Objection to form. 6 THE WITNESS: Sorry. Wow, sorry. 7 BY MS. PARFITT: 8 Q We had a chorus. 9 A Yeah. 10 No, you don't need to prove it, but 11 it's -- 12 Q You don't need to prove mechanism. 13 A You don't need to prove mechanism in 14 order to establish causation, but it's hard to get 15 there for a low observed risk if you don't have 16 biological plausibility. 17 Q I'll take that back -- yes, I'm sorry. 18 I hope I didn't ask you this before, but 19 is biological plausibility the same as proof of 20 mechanism? 21 MR. LOCKE: Objection. 22 MS. BROWN: Objection to the form of the 23 question. 24 THE WITNESS: Proof of -- I don't know 25 if I would use the -- so "proof of mechanism"</p>	<p style="text-align: right;">Page 448</p> <p>1 exposure can lead to the outcome that you're 2 interested in. 3 BY MS. PARFITT: 4 Q Okay. Doctor, from your review of the 5 peer-reviewed scientific literature, have you read 6 where study authors who have actually looked at 7 the issue of migration and other biological 8 plausible methods by which talc can get to the 9 ovary? 10 A I guess -- 11 MS. BROWN: I object. I don't 12 understand. 13 THE WITNESS: I mean I've looked at both 14 the human and the animal studies that I could find 15 cited on the topic. And -- and you said that 16 talc -- talc can get to the ovary? 17 BY MS. PARFITT: 18 Q Mm-hmm. 19 A Because, you know, some are not talc, 20 right. There -- there are other kinds of 21 particles or substances. And so I've looked at 22 both the animal and the human studies that I could 23 find. 24 Q And in those studies that you have 25 reviewed, have you seen where those authors who</p>
<p style="text-align: right;">Page 447</p> <p>1 sounds like a term in a way, but maybe not one 2 that's in my vocabulary. Like people talk about 3 proof of concept just as a study design, which -- 4 I don't know if that's the same thing, but I 5 don't -- I don't -- I don't know "proof of 6 mechanism" as a -- as a term. 7 (Counsel conferring.) 8 MS. PARFITT: Let's go off the record 9 for a moment. 10 THE VIDEOGRAPHER: The time is 5:30 p.m. 11 We're going off the record. 12 (Recess.) 13 THE VIDEOGRAPHER: The time is 5:37 p.m. 14 and we're back on the record. 15 BY MS. PARFITT: 16 Q Doctor, what is your definition of 17 "biological plausibility"? 18 MS. BROWN: Objection. Asked and 19 answered. 20 THE WITNESS: I don't have a single one. 21 I think it's in my report somewhere, or at least 22 what I tried to capture from Bradford Hill's 23 statement, but in a general sense, you know, being 24 evidence that whatever -- if we're talking about 25 an exposure, that there is a pathway by which that</p>	<p style="text-align: right;">Page 449</p> <p>1 have studied the issue of biological plausibility 2 and mechanisms by which talc can get to the ovary 3 have concluded in their articles that that is 4 indeed a pathway? 5 MS. BROWN: Objection. 6 MR. LOCKE: Objection. 7 MS. BROWN: Misstates his testimony and 8 the documents. 9 THE WITNESS: That there is -- well, I 10 guess we've got to -- we'd have to look at each 11 one, right. Because, I mean, there's ones like, 12 for example, you know, if we're talking about 13 humans, like where women are basically placed 14 upside down in a -- in an usual position and 15 having something deposited directly into their 16 vagina, and then that may or may not then migrate 17 to their ovaries, but that wouldn't be the same as 18 saying that's a plausible mechanism for applying 19 something to the perineum and then finding it in 20 the ovaries. 21 And then I just want to -- I don't have 22 a lot to say about it, but I would just say with 23 the animals, it looks like certain animals that 24 application of -- of particles does, and then in 25 others it doesn't migrate. And then so I -- I</p>

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<p style="text-align: right;">Page 450</p> <p>1 took that as kind of mixed evidence that even in 2 animals, assuming that there is an appropriate 3 animal model, that they're not getting the same 4 answer based on which animal it is. 5 BY MS. PARFITT: 6 Q Does exposure of a disease have to be 7 proven in order to have a biologically plausible 8 mechanism? 9 MS. BROWN: Objection to the form. 10 MR. LOCKE: Objection. 11 THE WITNESS: So I don't know if I 12 understand that. So are you saying that -- so say 13 it again. I'm sorry. 14 BY MS. PARFITT: 15 Q Sure. It was probably a bad question. 16 MS. BROWN: The realtime -- 17 BY MS. PARFITT: 18 Q Does one need -- does a scientist need 19 to know the precise mechanism in order to 20 determine whether or not it's biologically 21 plausible for some toxin to cause some disease? 22 MS. BROWN: Objection to the form. 23 MR. LOCKE: Objection. 24 THE WITNESS: So "precise" might be a -- 25 a term that matters, but -- but it can be a work</p>	<p style="text-align: right;">Page 452</p> <p>1 MS. BROWN: Objection to the form. 2 MR. LOCKE: Objection. 3 THE WITNESS: So I -- I looked -- for 4 all the things that we talked about -- I don't 5 know which ones we're talking about now in terms 6 of the epidemiology studies. 7 BY MS. PARFITT: 8 Q Correct. 9 A So I've seen some that do and some that 10 don't propose that. Some I think are -- and I'm 11 paraphrasing -- but are sort of more along the 12 lines of we just don't know or there's a lot more 13 work needed, and -- and things of that sort. 14 Q Are there a lot on the lines of 15 migration of talc -- excuse me. 16 Are there a lot of articles that you've 17 reviewed where they have -- authors have stated 18 that talc can migrate to the ovaries? 19 A I wouldn't say -- 20 MS. BROWN: Objection. 21 THE WITNESS: I wouldn't say a lot. And 22 I haven't seen anything as strong as that FDA 23 statement, you know, I mean, where -- where 24 there's some, you know, certainty that is coupled 25 with that kind of a statement.</p>
<p style="text-align: right;">Page 451</p> <p>1 in progress in the sense that you can have some 2 information or no information or lots of 3 information. So there can be, you know, quite a 4 spectrum of information you would have about the 5 plausibility. 6 BY MS. PARFITT: 7 Q I think what I'm asking is, does the 8 mechanism of disease need to be proven in order to 9 find causality? 10 MS. BROWN: Objection to the form. 11 THE WITNESS: I -- I think we keep doing 12 this over and over, because this -- I think -- I 13 think this is the same -- unless it's meant to be 14 different, like I don't know how to answer that 15 differently. It's -- you know, obviously it 16 doesn't have to be proven, but it certainly is 17 important. And when you have a very small 18 estimated risk, then it becomes even more 19 important. 20 BY MS. PARFITT: 21 Q Okay. Have you seen in the literature 22 that you've reviewed numerous authors who have 23 proposed a biologically plausible mechanism by 24 which talcum powder products can cause ovarian 25 cancer?</p>	<p style="text-align: right;">Page 453</p> <p>1 BY MS. PARFITT: 2 Q But you've certainly seen where the 3 authors have opined and discussed biologically 4 plausible mechanism by -- mechanisms by which 5 talcum powder products can cause ovarian cancer. 6 MR. LOCKE: Objection. 7 MS. BROWN: Objection. Continues to 8 misstate his testimony. 9 THE WITNESS: What's -- what's different 10 about that than what I already answered? 11 BY MS. PARFITT: 12 Q Well, what I'm trying to get at is, 13 whether or not you believe it or don't believe it, 14 I'm simply trying to understand from you whether 15 or not in your read of the scientific literature 16 have you seen where authors who have actually 17 studied this topic where they have determined and 18 written in their reports that there are 19 biologically plausible mechanisms by which talc 20 can migrate to the ovaries? 21 MR. LOCKE: Objection. 22 MS. BROWN: No, objection. He's 23 answered this a hundred times, and it's -- 24 BY MS. PARFITT: 25 Q And if it's no, then it's no. If you've</p>

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<p>1 seen it, you've seen it. If you dispute it, you</p> <p>2 dispute it.</p> <p>3 A Well, it's -- it's none of those.</p> <p>4 But you just said reports. Does that --</p> <p>5 are we now talking about expert reports or are --</p> <p>6 Q No.</p> <p>7 A -- we still talking about --</p> <p>8 Q No, we're still talking --</p> <p>9 A Okay. We're talking about like</p> <p>10 peer-reviewed publications?</p> <p>11 Q That's right.</p> <p>12 A So I've seen a mixture, yeah. It's like</p> <p>13 when you look at the epi literature, I mean the --</p> <p>14 the way I read it is like -- is, you know, an</p> <p>15 epidemiologist is supposed to be able to get up to</p> <p>16 speed without becoming an expert in absolutely</p> <p>17 everything, right?</p> <p>18 So I already told you I'm not a cancer</p> <p>19 biologist, but I do count on the authors to set</p> <p>20 the stage with the introduction and then interpret</p> <p>21 their findings and the discussion and sort of take</p> <p>22 us at least partway towards there.</p> <p>23 So even the recent meta-analysis, if you</p> <p>24 look at Berge or Burge (phonetic), however you say</p> <p>25 that, and Penninkilampi, you know, they talk about</p>	<p>1 probably means one thing in the world in general.</p> <p>2 I think if you're talking about Rothman, yeah,</p> <p>3 Rothman has written about that --</p> <p>4 BY MS. PARFITT:</p> <p>5 Q Right.</p> <p>6 A -- and about it being simply a</p> <p>7 competition of sort of counting those that are</p> <p>8 significant and those that are not.</p> <p>9 I didn't see that. I think the way I</p> <p>10 described it I think was -- was the way I</p> <p>11 approached it, which said some of the information</p> <p>12 that's available is that some of the studies were</p> <p>13 statistically significant and some weren't. It's</p> <p>14 informative, but it's not literally the same as</p> <p>15 saying, I'm just going to count them up and stop</p> <p>16 there.</p> <p>17 Q Because that would be improper, correct?</p> <p>18 MS. BROWN: Objection.</p> <p>19 THE WITNESS: To only do that, yes.</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Okay. All right. Let me ask a couple</p> <p>22 of question -- questions.</p> <p>23 What is the minimal level of exposure to</p> <p>24 cigarette smoke in terms of cigarette smoke at</p> <p>25 home that's necessary to cause lung cancer?</p>
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<p>1 there -- there being uncertainty about the</p> <p>2 mechanism. So I'm just saying even as recently as</p> <p>3 the -- the very latest meta-analysis, there's</p> <p>4 uncertainty expressed.</p> <p>5 Q Do you see uncertainty being expressed</p> <p>6 by biologically plausible mechanisms?</p> <p>7 MS. BROWN: Objection.</p> <p>8 THE WITNESS: Well, I don't know if</p> <p>9 they're plausible or not. I mean that's the whole</p> <p>10 point, right? You know, I mean you can say</p> <p>11 something, but it doesn't make it true.</p> <p>12 BY MS. PARFITT:</p> <p>13 Q You reminded me of something. In your</p> <p>14 review of the various case-control studies, did</p> <p>15 you exercise a process known as vote counting?</p> <p>16 MS. BROWN: Objection.</p> <p>17 THE WITNESS: No.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q You did not?</p> <p>20 A I did not.</p> <p>21 Q That would be improper to do so,</p> <p>22 correct?</p> <p>23 MS. BROWN: Objection.</p> <p>24 THE WITNESS: Well, if we're talking --</p> <p>25 so I guess, just to be clear, so vote counting</p>	<p>1 MS. BROWN: Form.</p> <p>2 THE WITNESS: I do not know.</p> <p>3 BY MS. PARFITT:</p> <p>4 Q Okay. What is the minimal level of</p> <p>5 exposure to asbestos fibers inhaled that is</p> <p>6 sufficient to cause ovarian cancer?</p> <p>7 MS. BROWN: Form.</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: We -- we did that before.</p> <p>10 I don't -- I don't have any more information than</p> <p>11 what I did, like meaning, you know, I have some --</p> <p>12 some guideposts like the -- the Whitnum 40</p> <p>13 fiber/cc years of -- of crocidolite, which did not</p> <p>14 seem to be adequate to cause it.</p> <p>15 And then, you know, when we looked at</p> <p>16 the IARC, I didn't -- even when you and I looked</p> <p>17 at it together, I didn't see information that</p> <p>18 talked about what dose would be required.</p> <p>19 BY MS. PARFITT:</p> <p>20 Q Okay. Same question. What's the</p> <p>21 minimal level of exposure to asbestos fibers</p> <p>22 inhaled that is sufficient to cause mesothelioma?</p> <p>23 MS. BROWN: Objection.</p> <p>24 MR. LOCKE: Objection.</p> <p>25 THE WITNESS: Pleural or peritoneal</p>

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<p style="text-align: right;">Page 458</p> <p>1 or --</p> <p>2 BY MS. PARFITT:</p> <p>3 Q Pleural.</p> <p>4 A So the -- so the amount for pleural</p> <p>5 mesothelioma is -- and did you say fiber type or</p> <p>6 you didn't mention fiber type?</p> <p>7 Q I didn't. I just said fibers.</p> <p>8 A Okay. So it would matter fiber type.</p> <p>9 If it's chrysotile predominant, then above 200 to</p> <p>10 400 fiber/cc years would be, you know, one</p> <p>11 estimate of the dose. If it's crocidolite, you</p> <p>12 know, you could divide that by 500. And if it's</p> <p>13 amosite, by a hundred, and other amphiboles, you</p> <p>14 know, somewhere in between those sort of ranges.</p> <p>15 And so, you know, I think for</p> <p>16 amphiboles, above like the single digit fiber/cc</p> <p>17 years, and for chrysotile, above the couple of</p> <p>18 like 200 to 400 fiber/cc years.</p> <p>19 Q Is it true that the dose-response curve</p> <p>20 for any genotoxic carcinogen intersects with zero?</p> <p>21 MS. BROWN: Objection to the form.</p> <p>22 THE WITNESS: Well, there's got to be a</p> <p>23 zero point if there's zero exposure, right? If</p> <p>24 there's literally zero exposure, then there can't</p> <p>25 be -- there can't be a signal from that zero.</p>	<p style="text-align: right;">Page 460</p> <p>1 Q Okay. You criticize the plaintiffs'</p> <p>2 experts for what you called a muted examination of</p> <p>3 the case-control studies that they reviewed.</p> <p>4 Do you remember saying that in your</p> <p>5 report?</p> <p>6 A I don't remember that word, but it's --</p> <p>7 it makes a lot of sense to me.</p> <p>8 Q Okay. Where in your port -- report did</p> <p>9 you set forth all of the limitations and</p> <p>10 weaknesses of the cohort studies of talcum --</p> <p>11 talcum powder products and asbestos -- and ovarian</p> <p>12 cancer?</p> <p>13 A Well, there's a bunch, right. So --</p> <p>14 Q Well, where did you --</p> <p>15 A I'm telling you.</p> <p>16 Q -- provide us in your report that</p> <p>17 information --</p> <p>18 A I'm telling you.</p> <p>19 MS. BROWN: Let him finish --</p> <p>20 THE WITNESS: I understand your</p> <p>21 question.</p> <p>22 MS. BROWN: -- and answer your question.</p> <p>23 THE WITNESS: So one of the criticisms,</p> <p>24 which I think is pretty profound, which is the</p> <p>25 lack of a validated measure of talcum powder</p>
<p style="text-align: right;">Page 459</p> <p>1 BY MS. PARFITT:</p> <p>2 Q What does the -- what does it mean if a</p> <p>3 dose-response curve intersects zero?</p> <p>4 MS. BROWN: Form.</p> <p>5 BY MS. PARFITT:</p> <p>6 Q What does that mean?</p> <p>7 A It's not a term that's familiar. I</p> <p>8 mean, it's just -- I'm not sure -- if you've got</p> <p>9 zero exposure, you can't have any outcome from</p> <p>10 that. So I -- I assume that's what we're talking</p> <p>11 about is just like a -- like a no exposure</p> <p>12 estimate.</p> <p>13 If you're talking about like -- the</p> <p>14 place I've seen people talk about it is like with</p> <p>15 low doses of things and what happens, you know,</p> <p>16 below the concentration or the level at which</p> <p>17 there's known effects, then what happens between</p> <p>18 there and zero. But if it's literally zero -- if</p> <p>19 there's literally zero exposure, it's got to be</p> <p>20 zero outcome.</p> <p>21 (Counsel conferring.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Okay. You reviewed the cohort studies</p> <p>24 in this case, correct?</p> <p>25 A The three -- three cohort studies.</p>	<p style="text-align: right;">Page 461</p> <p>1 exposure that could have someone estimate whether</p> <p>2 or not somebody is exposed at all or whether or</p> <p>3 not there's a dose-response, and that applies to</p> <p>4 all the studies, right. So that's uniformly</p> <p>5 applied to whether they're case-control studies</p> <p>6 or -- or cohort studies.</p> <p>7 BY MS. PARFITT:</p> <p>8 Q That would be the exposure</p> <p>9 misclassification.</p> <p>10 MS. BROWN: Objection.</p> <p>11 THE WITNESS: No, no, no. So it would</p> <p>12 be -- you could misclassify it, but it -- but what</p> <p>13 I'm talking about is, that in order to measure an</p> <p>14 exposure, you need a valid measure of that</p> <p>15 exposure. That doesn't exist, or at least if it</p> <p>16 exists, it hasn't been employed in the -- in the</p> <p>17 published literature. And that applies to the</p> <p>18 cohort studies and the case controls.</p> <p>19 What I -- what I did was I tried to</p> <p>20 actually not denigrate any of the study designs.</p> <p>21 I thought that was appalling. You know, when you</p> <p>22 talk about where this came from, you know, to sort</p> <p>23 of single out the cohort studies repeatedly by</p> <p>24 the -- by the plaintiffs' expert and say, you</p> <p>25 know, This is a terrible design, or this is</p>

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<p style="text-align: right;">Page 462</p> <p>1 terrible for whatever reason, it's extraordinary, 2 and it's -- to me it's unprecedented for -- for 3 epidemiologists or other healthcare professionals 4 to sort of look at cohort studies and find that 5 those are so awful, and that case-control studies 6 are suddenly so sturdy. It doesn't make any 7 sense. 8 So -- so for me, like the task wasn't 9 really so much -- I wasn't trying to criticize 10 either form of the study, but just to point out 11 realistically that there are biases, that there 12 are confounding issues, and -- and things of 13 that -- that sort. 14 BY MS. PARFITT: 15 Q In your review of the literature for 16 purposes of your opinions today, did you see 17 evidence from any of the studies that you read 18 that there was a dose-response associated between 19 talcum powder products and ovarian cancer? 20 A So in total, no. In a couple of 21 studies, there are purported dose-response 22 findings, right. So the latest Cramer study is an 23 example. There may have been another, but there 24 are so many studies that show absolutely the 25 opposite, meaning either flat dose-response,</p>	<p style="text-align: right;">Page 464</p> <p>1 Q Okay. So you would agree with me there 2 are studies in the peer-reviewed literature that 3 have demonstrated a dose-response between talcum 4 powder products and ovarian cancer? 5 MS. BROWN: Objection -- 6 MR. LOCKE: Objection. 7 MS. BROWN: -- to the form. 8 MS. PARFITT: Let him answer, please. 9 MS. BROWN: I get to object. 10 THE WITNESS: I think just a couple. 11 MS. PARFITT: Let's go off the record. 12 THE VIDEOGRAPHER: The time is 5:53 p.m. 13 We're going off the record. 14 (Recess.) 15 THE VIDEOGRAPHER: The time is 5:58 p.m. 16 We're back on the record. 17 MR. HEASLIP: Can we go off for one 18 moment? I apologize. 19 THE VIDEOGRAPHER: The time is 5:58 p.m. 20 We're going back off the record. 21 (A discussion was held off the record.) 22 THE VIDEOGRAPHER: The time is 5:59 p.m. 23 We're back on the record. 24 CROSS-EXAMINATION 25 BY MR. FINCH:</p>
<p style="text-align: right;">Page 463</p> <p>1 upside down dose-response, zig-zaggy, haphazard 2 dose-response. So I would say looking at the 3 evidence in total, it's a mess. I mean it's 4 certainly not supportive. 5 And I'll you the truth, if you go back 6 to -- like to 2000 -- and I know we're in a hurry, 7 so I will try to talk a little faster -- but the 8 Rothman -- the Rothman review, at least up until 9 2000, they -- they plotted out all the 10 dose-response they found, and they found an 11 inverse relationship overall, which is one of the 12 things they found to be inconsistent with there 13 being causation. 14 So I think, you know, from 1982, when 15 the first case-control study was published, to 16 2000, at least when it's assessed by Rothman and 17 his colleagues, is actually upside down. 18 Q What about Terry? Terry in 2013 19 reported a dose-response, did they not? 20 MS. BROWN: Objection to the form. 21 THE WITNESS: I don't remember what they 22 showed. I don't -- I don't doubt you, but I -- 23 but there's just -- there's a couple of studies 24 that have demonstrated that. 25 BY MS. PARFITT:</p>	<p style="text-align: right;">Page 465</p> <p>1 Q Good afternoon, Dr. Diette. My name is 2 Nate Finch. You and I have met before, correct? 3 A Yes. 4 Q You were asked a question about the 5 dose-response curve to genotoxic carcinogens. Do 6 you recall that question? 7 A I do. 8 Q And your answer was something to the 9 effect of if the dose was zero, then it would be 10 an intersection of zero. 11 Do you recall that answer? 12 A Something like that. 13 Q All right. I want you to assume that 14 we're talking about a dose-response curve where 15 there is a positive dose, not a dose of zero. 16 Your typical dose-response curve looks something 17 like this (indicating), right, with dose on the 18 X-axis and response on the Y-axis? 19 A You can draw it that way. 20 MS. MILLER: Is that a exhibit? 21 MR. FINCH: You can mark it as an 22 exhibit. It's got somebody's notes on the back of 23 it, but... 24 BY MR. FINCH: 25 Q Isn't it true, Dr. Diette, that for a</p>

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<p style="text-align: right;">Page 466</p> <p>1 genotoxic carcinogen where there is a positive 2 dose, the dose-response curve always intersects 3 with zero? 4 MS. BROWN: Objection to form. 5 THE WITNESS: That's not something that 6 I say. I mean I don't -- people may say that, but 7 I -- I think when we're talking about -- like zero 8 is zero, right. So zero exposure means zero risk. 9 BY MR. FINCH: 10 Q I'm not -- I'm not talking about zero. 11 MS. BROWN: Wait, let him finish, 12 please. 13 THE WITNESS: Well, I know. That's what 14 I'm talking about when I -- when I hear that 15 question. 16 BY MR. FINCH: 17 Q All right. So if someone were to 18 testify when you're talking about a genotoxic 19 carcinogen where there is a positive exposure, 20 there -- the dose-response curve intersects with 21 zero, meaning that there -- isn't it true that 22 that means that there -- at any level of exposure, 23 there's an excess risk of cancer for a genotoxic 24 carcinogen? 25 MS. BROWN: Objection to the form.</p>	<p style="text-align: right;">Page 468</p> <p>1 about the sort of mechanical process of writing 2 your report. Do you remember that? 3 A I do. 4 Q And to be clear, Doctor, did you write 5 every substantive word of the expert report that 6 we've marked as an exhibit in this case? 7 A To the -- yes, everything substantive. 8 Q Did MSA or Medical Science Affiliates 9 make any substantive contributions to your expert 10 report in this proceeding? 11 A No. 12 Q You spoke a little bit earlier today 13 about some administrative support that you 14 received from MSA. Do you remember that? 15 A I do. 16 Q And tell us what you meant by 17 "administrative support." 18 A So by "administrative support," I meant, 19 you know, gathering -- like collating materials 20 for me, helping to -- to format the report, you 21 know, putting -- you know, putting the reference 22 citations in correctly. You know, creating the -- 23 the list of reliance documents at the end. You 24 know, things of that sort. And then -- and then 25 generating invoices.</p>
<p style="text-align: right;">Page 467</p> <p>1 THE WITNESS: So I don't know. That may 2 be part of some field that's not my field. But I 3 -- but in the fields that I work in, I recognize 4 that you need a certain amount of exposure in 5 order to cause a disease, including cancer. 6 BY MR. FINCH: 7 Q Okay. But you cannot dispute that 8 genotoxic carcinogens, the dose-response curve 9 intersects with zero. You haven't studied that 10 issue; is that correct? 11 MR. LOCKE: Objection. 12 MS. BROWN: Objection to the form. 13 THE VIDEOGRAPHER: Seven hours. 14 MS. BROWN: You're done. Wait. 15 THE WITNESS: So I mean, my answer is 16 the same as it was before. 17 MS. BROWN: I can ask from here. 18 (A discussion was held off the record.) 19 CROSS-EXAMINATION 20 BY MS. BROWN: 21 Q Good evening, Dr. Diette. 22 A Hi. 23 Q Just a couple of quick questions, and we 24 will get you on your way. 25 We had some discussion earlier today</p>	<p style="text-align: right;">Page 469</p> <p>1 I'm trying to think what else. 2 Whatever -- whatever I said earlier was the -- was 3 the full list, I think. 4 Q You also mentioned earlier today 5 receiving some editorial support from the folks at 6 MSA. Tell us what you meant by that. 7 A So to look for typos or -- I gave the 8 example of like where I had a really long 9 paragraph, and they broke it up with bullets to 10 make it look more readable, that sort of thing, 11 and -- and just making this actually have the 12 physical appearance that it does. 13 Q Did MSA provide anything other than 14 administrative formatting type support in 15 connection with your report in this case? 16 A No. 17 Q If someone were to suggest that the 18 opinions in your expert report are not entirely 19 your own, would that be the truth? 20 A I'm sorry. I was reading that going by, 21 and I didn't listen. 22 Q Sure. If someone were to suggest that 23 some of the opinions in your expert report are not 24 entirely your own, would that be the truth? 25 A No.</p>

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<p style="text-align: right;">Page 470</p> <p>1 MS. PARFITT: Objection. 2 THE WITNESS: They're -- they're all my 3 opinions. 4 BY MS. BROWN: 5 Q If someone were to suggest that MSA 6 wrote some of the substantive pieces of your 7 report, would that be the truth? 8 MS. PARFITT: Objection. 9 THE WITNESS: No. 10 MS. BROWN: Thanks very much for your 11 time, Dr. Diette. I have no further questions. 12 MS. PARFITT: Anybody? No. Thank you. 13 Dr. Diette, thank you very much. 14 THE WITNESS: Thank you. 15 MS. PARFITT: I appreciate it. 16 THE VIDEOGRAPHER: The time is 6:04 17 p.m., April 9th, 2019. Going off the record, 18 completing the videotaped deposition. 19 (Whereupon, the deposition of 20 GREGORY B. DIETTE, M.D. was 21 concluded at 6:04 p.m.) 22 23 24 25</p>	<p style="text-align: right;">Page 472</p> <p>1 INSTRUCTIONS TO WITNESS 2 Please read your deposition over carefully and 3 make any necessary corrections. You should state 4 the reason in the appropriate space on the errata 5 sheet for any corrections that are made. 6 After doing so, please sign the errata sheet 7 and date it. 8 You are signing same subject to the changes 9 you have noted on the errata sheet, which will be 10 attached to your deposition. It is imperative 11 that you return the original errata sheet to the 12 deposing attorney within thirty (30) days of 13 receipt of the deposition transcript by you. If 14 you fail to do so, the deposition transcript may 15 be deemed to be accurate and may be used in court. 16 17 18 19 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 471</p> <p>1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER 2 The undersigned Certified Shorthand Reporter 3 does hereby certify: 4 That the foregoing proceeding was taken before 5 me at the time and place therein set forth, at 6 which time the witness was duly sworn; That the 7 testimony of the witness and all objections made 8 at the time of the examination were recorded 9 stenographically by me and were thereafter 10 transcribed, said transcript being a true and 11 correct copy of my shorthand notes thereof; That 12 the dismantling of the original transcript will 13 void the reporter's certificate. 14 In witness thereof, I have subscribed my name 15 this date: April 10, 2019. 16 17 _____ 18 LESLIE A. TODD, CSR, RPR 19 Certificate No. 5129 20 (The foregoing certification of 21 this transcript does not apply to any 22 reproduction of the same by any means, 23 unless under the direct control and/or 24 supervision of the certifying reporter.) 25</p>	<p style="text-align: right;">Page 473</p> <p>1 ----- 2 E R R A T A 3 ----- 4 PAGE LINE CHANGE 5 _____ 6 REASON: _____ 7 _____ 8 REASON: _____ 9 _____ 10 REASON: _____ 11 _____ 12 REASON: _____ 13 _____ 14 REASON: _____ 15 _____ 16 REASON: _____ 17 _____ 18 REASON: _____ 19 _____ 20 REASON: _____ 21 _____ 22 REASON: _____ 23 _____ 24 REASON: _____ 25</p>

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1 ACKNOWLEDGMENT OF DEPONENT
2 I, _____, do hereby
3 certify that I have read the foregoing pages, and
4 that the same is a correct transcription of the
5 answers given by me to the questions therein
6 propounded, except for the corrections or changes
7 in form or substance, if any, noted in the
8 attached Errata Sheet.
9

10 _____
11 GREGORY B. DIETTE, M.D. DATE
12

13
14 Subscribed and sworn to
15 before me this
16 _____ day of _____, 20____.
17 My commission expires: _____
18 _____

19 Notary Public
20
21
22
23
24
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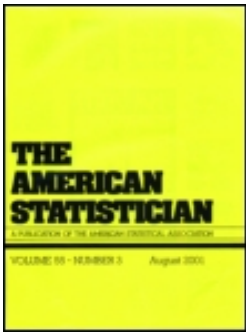
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Exhibit 142



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The ASA's Statement on p -Values: Context, Process, and Purpose

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EDITORIAL

The ASA's Statement on p -Values: Context, Process, and Purpose

In February 2014, George Cobb, Professor Emeritus of Mathematics and Statistics at Mount Holyoke College, posed these questions to an ASA discussion forum:

Q: Why do so many colleges and grad schools teach $p = 0.05$?

A: Because that's still what the scientific community and journal editors use.

Q: Why do so many people still use $p = 0.05$?

A: Because that's what they were taught in college or grad school.

Cobb's concern was a long-worrisome circularity in the sociology of science based on the use of bright lines such as $p < 0.05$: "We teach it because it's what we do; we do it because it's what we teach." This concern was brought to the attention of the ASA Board.

The ASA Board was also stimulated by highly visible discussions over the last few years. For example, ScienceNews (Siegfried 2010) wrote: "It's science's dirtiest secret: The 'scientific method' of testing hypotheses by statistical analysis stands on a flimsy foundation." A November 2013, article in Phys.org Science News Wire (2013) cited "numerous deep flaws" in null hypothesis significance testing. A ScienceNews article (Siegfried 2014) on February 7, 2014, said "statistical techniques for testing hypotheses ... have more flaws than Facebook's privacy policies." A week later, statistician and "Simply Statistics" blogger Jeff Leek responded. "The problem is not that people use P -values poorly," Leek wrote, "it is that the vast majority of data analysis is not performed by people properly trained to perform data analysis" (Leek 2014). That same week, statistician and science writer Regina Nuzzo published an article in *Nature* entitled "Scientific Method: Statistical Errors" (Nuzzo 2014). That article is now one of the most highly viewed *Nature* articles, as reported by altmetric.com (<http://www.altmetric.com/details/2115792#score>).

Of course, it was not simply a matter of responding to some articles in print. The statistical community has been deeply concerned about issues of *reproducibility* and *replicability* of scientific conclusions. Without getting into definitions and distinctions of these terms, we observe that much confusion and even doubt about the validity of science is arising. Such doubt can lead to radical choices, such as the one taken by the editors of *Basic and Applied Social Psychology*, who decided to ban p -values (null hypothesis significance testing) (Trafimow and Marks 2015). Misunderstanding or misuse of statistical inference is only one cause of the "reproducibility crisis" (Peng 2015), but to our community, it is an important one.

When the ASA Board decided to take up the challenge of developing a policy statement on p -values and statistical significance, it did so recognizing this was not a lightly taken step. The ASA has not previously taken positions on specific matters of statistical practice. The closest the association has come to this is a statement on the use of value-added models (VAM) for educational assessment (Morganstein and Wasserstein

2014) and a statement on risk-limiting post-election audits (American Statistical Association 2010). However, these were truly policy-related statements. The VAM statement addressed a key educational policy issue, acknowledging the complexity of the issues involved, citing limitations of VAMs as effective performance models, and urging that they be developed and interpreted with the involvement of statisticians. The statement on election auditing was also in response to a major but specific policy issue (close elections in 2008), and said that statistically based election audits should become a routine part of election processes.

By contrast, the Board envisioned that the ASA statement on p -values and statistical significance would shed light on an aspect of our field that is too often misunderstood and misused in the broader research community, and, in the process, provides the community a service. The intended audience would be researchers, practitioners, and science writers who are not primarily statisticians. Thus, this statement would be quite different from anything previously attempted.

The Board tasked Wasserstein with assembling a group of experts representing a wide variety of points of view. On behalf of the Board, he reached out to more than two dozen such people, all of whom said they would be happy to be involved. Several expressed doubt about whether agreement could be reached, but those who did said, in effect, that if there was going to be a discussion, they wanted to be involved.

Over the course of many months, group members discussed what format the statement should take, tried to more concretely visualize the audience for the statement, and began to find points of agreement. That turned out to be relatively easy to do, but it was just as easy to find points of intense disagreement.

The time came for the group to sit down together to hash out these points, and so in October 2015, 20 members of the group met at the ASA Office in Alexandria, Virginia. The 2-day meeting was facilitated by Regina Nuzzo, and by the end of the meeting, a good set of points around which the statement could be built was developed.

The next 3 months saw multiple drafts of the statement, reviewed by group members, by Board members (in a lengthy discussion at the November 2015 ASA Board meeting), and by members of the target audience. Finally, on January 29, 2016, the Executive Committee of the ASA approved the statement.

The statement development process was lengthier and more controversial than anticipated. For example, there was considerable discussion about how best to address the issue of multiple *potential* comparisons (Gelman and Loken 2014). We debated at some length the issues behind the words "a p -value near 0.05 taken by itself offers only weak evidence against the null

hypothesis” (Johnson 2013). There were differing perspectives about how to characterize various alternatives to the p -value and in how much detail to address them. To keep the statement reasonably simple, we did not address alternative hypotheses, error types, or power (among other things), and not everyone agreed with that approach.

As the end of the statement development process neared, Wasserstein contacted Lazar and asked if the policy statement might be appropriate for publication in *The American Statistician* (TAS). After consideration, Lazar decided that TAS would provide a good platform to reach a broad and general statistical readership. Together, we decided that the addition of an online discussion would heighten the interest level for the TAS audience, giving an opportunity to reflect the aforementioned controversy.

To that end, a group of discussants was contacted to provide comments on the statement. You can read their statements in the online supplement, and a guide to those statements appears at the end of this editorial. We thank Naomi Altman, Douglas Altman, Daniel J. Benjamin, Yoav Benjamini, Jim Berger, Don Berry, John Carlin, George Cobb, Andrew Gelman, Steve Goodman, Sander Greenland, John Ioannidis, Joseph Horowitz, Valen Johnson, Michael Lavine, Michael Lew, Rod Little, Deborah Mayo, Michele Millar, Charles Poole, Ken Rothman, Stephen Senn, Dalene Stangl, Philip Stark and Steve Ziliak for sharing their insightful perspectives.

Of special note is the following article, which is a significant contribution to the literature about p -values and statistical significance.

Greenland, S., Senn, S.J., Rothman, K.J., Carlin, J.B., Poole, C., Goodman, S.N. and Altman, D.G.: “Statistical Tests, P -values, Confidence Intervals, and Power: A Guide to Misinterpretations.”

Though there was disagreement on exactly what the statement should say, there was high agreement that the ASA should be speaking out about these matters.

Let us be clear. Nothing in the ASA statement is new. Statisticians and others have been sounding the alarm about these matters for decades, to little avail. We hoped that a statement from the world’s largest professional association of statisticians would open a fresh discussion and draw renewed and vigorous attention to changing the practice of science with regards to the use of statistical inference.

Guide to the Online Supplemental Material to the ASA Statement on P -Values and Statistical Significance

Many of the participants in the development of the ASA statement contributed commentary about the statement or matters related to it. Their comments are posted as online supplements to the statement. We provide here a list of the supplemental articles.

Supplemental Material to the ASA Statement on P -Values and Statistical Significance

- *Altman, Naomi*: Ideas from multiple testing of high dimensional data provide insights about reproducibility and false discovery rates of hypothesis supported by p -values

- *Benjamin, Daniel J, and Berger, James O*: A simple alternative to p -values
- *Benjamini, Yoav*: It’s not the p -values’ fault
- *Berry, Donald A*: P -values are not what they’re cracked up to be
- *Carlin, John B*: Comment: Is reform possible without a paradigm shift?
- *Cobb, George*: ASA statement on p -values: Two consequences we can hope for
- *Gelman, Andrew*: The problems with p -values are not just with p -values
- *Goodman, Steven N*: The next questions: Who, what, when, where, and why?
- *Greenland, Sander*: The ASA guidelines and null bias in current teaching and practice
- *Ioannidis, John P.A.*: Fit-for-purpose inferential methods: abandoning/changing P -values versus abandoning/changing research
- *Johnson, Valen E.*: Comments on the “ASA Statement on Statistical Significance and P -values” and marginally significant p -values
- *Lavine, Michael, and Horowitz, Joseph*: Comment
- *Lew, Michael J*: Three inferential questions, two types of P -value
- *Little, Roderick J*: Discussion
- *Mayo, Deborah G*: Don’t throw out the error control baby with the bad statistics bathwater
- *Millar, Michele*: ASA statement on p -values: some implications for education
- *Rothman, Kenneth J*: Disengaging from statistical significance
- *Senn, Stephen*: Are P -Values the Problem?
- *Stangl, Dalene*: Comment
- *Stark, P.B.*: The value of p -values
- *Ziliak, Stephen T*: The significance of the ASA statement on statistical significance and p -values

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ASA Statement on Statistical Significance and P-Values

1. Introduction

Increased quantification of scientific research and a proliferation of large, complex datasets in recent years have expanded the scope of applications of statistical methods. This has created new avenues for scientific progress, but it also brings concerns about conclusions drawn from research data. The validity of scientific conclusions, including their reproducibility, depends on more than the statistical methods themselves. Appropriately chosen techniques, properly conducted analyses and correct interpretation of statistical results also play a key role in ensuring that conclusions are sound and that uncertainty surrounding them is represented properly.

Underpinning many published scientific conclusions is the concept of "statistical significance," typically assessed with an index called the p -value. While the p -value can be a useful statistical measure, it is commonly misused and misinterpreted. This has led to some scientific journals discouraging the use of p -values, and some scientists and statisticians recommending their abandonment, with some arguments essentially unchanged since p -values were first introduced.

In this context, the American Statistical Association (ASA) believes that the scientific community could benefit from a formal statement clarifying several widely agreed upon principles underlying the proper use and interpretation of the p -value. The issues touched on here affect not only research, but research funding, journal practices, career advancement, scientific education, public policy, journalism, and law. This statement does not seek to resolve all the issues relating to sound statistical practice, nor to settle foundational controversies. Rather, the statement articulates in nontechnical terms a few select principles that could improve the conduct or interpretation of quantitative science, according to widespread consensus in the statistical community.

2. What is a p -Value?

Informally, a p -value is the probability under a specified statistical model that a statistical summary of the data (e.g., the sample mean difference between two compared groups) would be equal to or more extreme than its observed value.

3. Principles

1. **P -values can indicate how incompatible the data are with a specified statistical model.**

A p -value provides one approach to summarizing the incompatibility between a particular set of data and

a proposed model for the data. The most common context is a model, constructed under a set of assumptions, together with a so-called "null hypothesis." Often the null hypothesis postulates the absence of an effect, such as no difference between two groups, or the absence of a relationship between a factor and an outcome. The smaller the p -value, the greater the statistical incompatibility of the data with the null hypothesis, if the underlying assumptions used to calculate the p -value hold. This incompatibility can be interpreted as casting doubt on or providing evidence against the null hypothesis or the underlying assumptions.

2. **P -values do not measure the probability that the studied hypothesis is true, or the probability that the data were produced by random chance alone.**

Researchers often wish to turn a p -value into a statement about the truth of a null hypothesis, or about the probability that random chance produced the observed data. The p -value is neither. It is a statement about data in relation to a specified hypothetical explanation, and is not a statement about the explanation itself.

3. **Scientific conclusions and business or policy decisions should not be based only on whether a p -value passes a specific threshold.**

Practices that reduce data analysis or scientific inference to mechanical "bright-line" rules (such as " $p < 0.05$ ") for justifying scientific claims or conclusions can lead to erroneous beliefs and poor decision making. A conclusion does not immediately become "true" on one side of the divide and "false" on the other. Researchers should bring many contextual factors into play to derive scientific inferences, including the design of a study, the quality of the measurements, the external evidence for the phenomenon under study, and the validity of assumptions that underlie the data analysis. Pragmatic considerations often require binary, "yes-no" decisions, but this does not mean that p -values alone can ensure that a decision is correct or incorrect. The widespread use of "statistical significance" (generally interpreted as " $p \leq 0.05$ ") as a license for making a claim of a scientific finding (or implied truth) leads to considerable distortion of the scientific process.

4. **Proper inference requires full reporting and transparency**

P -values and related analyses should not be reported selectively. Conducting multiple analyses of the data and reporting only those with certain p -values (typically those passing a significance threshold) renders the

reported p -values essentially uninterpretable. Cherry-picking promising findings, also known by such terms as data dredging, significance chasing, significance questing, selective inference, and “ p -hacking,” leads to a spurious excess of statistically significant results in the published literature and should be vigorously avoided. One need not formally carry out multiple statistical tests for this problem to arise: Whenever a researcher chooses what to present based on statistical results, valid interpretation of those results is severely compromised if the reader is not informed of the choice and its basis. Researchers should disclose the number of hypotheses explored during the study, all data collection decisions, all statistical analyses conducted, and all p -values computed. Valid scientific conclusions based on p -values and related statistics cannot be drawn without at least knowing how many and which analyses were conducted, and how those analyses (including p -values) were selected for reporting.

5. A p -value, or statistical significance, does not measure the size of an effect or the importance of a result.

Statistical significance is not equivalent to scientific, human, or economic significance. Smaller p -values do not necessarily imply the presence of larger or more important effects, and larger p -values do not imply a lack of importance or even lack of effect. Any effect, no matter how tiny, can produce a small p -value if the sample size or measurement precision is high enough, and large effects may produce unimpressive p -values if the sample size is small or measurements are imprecise. Similarly, identical estimated effects will have different p -values if the precision of the estimates differs.

6. By itself, a p -value does not provide a good measure of evidence regarding a model or hypothesis.

Researchers should recognize that a p -value without context or other evidence provides limited information. For example, a p -value near 0.05 taken by itself offers only weak evidence against the null hypothesis. Likewise, a relatively large p -value does not imply evidence in favor of the null hypothesis; many other hypotheses may be equally or more consistent with the observed data. For these reasons, data analysis should not end with the calculation of a p -value when other approaches are appropriate and feasible.

4. Other Approaches

In view of the prevalent misuses of and misconceptions concerning p -values, some statisticians prefer to supplement or even replace p -values with other approaches. These include methods that emphasize estimation over testing, such as confidence, credibility, or prediction intervals; Bayesian methods; alternative measures of evidence, such as likelihood ratios or Bayes Factors; and other approaches such as decision-theoretic modeling and false discovery rates. All these measures and approaches rely on further assumptions, but they may more directly address the size of an effect (and its associated uncertainty) or whether the hypothesis is correct.

5. Conclusion

Good statistical practice, as an essential component of good scientific practice, emphasizes principles of good study design and conduct, a variety of numerical and graphical summaries of data, understanding of the phenomenon under study, interpretation of results in context, complete reporting and proper logical and quantitative understanding of what data summaries mean. No single index should substitute for scientific reasoning.

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